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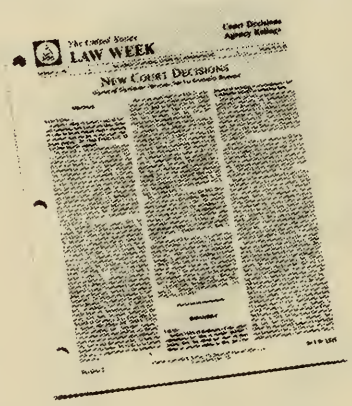
ARTICLES

NOTES

Decisions, Decisions, Decisions.



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Second Wind for the Indiana Bill of Rights*

Chief Justice Randall T. Shepard**

We assemble this evening on the two hundredth anniversary of the national debate over what to include in the federal Bill of Rights. Inextricably tied to that debate was the key role which our nation's founders believed the states should play in the protection of individual liberties against the excesses of government. The role of states, state courts and state constitutions requires care and tending. As Justice Clark wrote in *Mapp v. Ohio*:[1] "Nothing can destroy a government more quickly than its failure to observe its own laws, or worse, its disregard of the charter of its own existence."[2]

You will recall that it was only the promise of the federalists that they would support a federal bill of rights which brought the last two key states, Virginia and New York, into the new union. The anti-federalists had attacked the new constitution on the grounds that it would permit the new government too much control over the lives of individual citizens. Americans felt comfortable that they could live free lives with few threats from the state capital, but they feared the unchecked power of a new and distant sovereign. Even the promise of a series of amendments spelling out individual freedoms managed to carry the day in New York by only three votes.

As people like Jefferson, Sherman, and Madison began to think about the shape such a federal bill of rights should take, they had ample opportunity for borrowing. Many provisions in such charters as the

*This Article is a slightly edited version, with footnotes, of a speech to the annual meeting of the Indiana Civil Liberties Union on September 17, 1988. It was delivered in memory of Sydney L. Berger, one of Indiana's leading civil libertarians, who died in Evansville on July 31, 1988.

**Chief Justice of Supreme Court of Indiana. B.A., Princeton University, 1969; J.D., Yale University, 1972.

1. 367 U.S. 643 (1961).
2. *Id.* at 659.

Virginia Declaration of Rights became part and parcel of the new proposed amendments.

Notwithstanding the prompt adoption of ten amendments to the Constitution of the United States, the bills of rights in the state constitutions remained the principal force in American civil liberties for a century and a half. The federal Bill of Rights, after all, was designed to protect people against the national government. If there had ever been any doubt that it was not a limitation on state action, that doubt vanished when John Barron argued in the Supreme Court of the United States that the City of Baltimore had violated the Fifth Amendment. Chief Justice Marshall was not impressed: "The question thus presented is, we think, of great importance, but not of much difficulty."[3]

Indeed, even after the adoption of the Civil War amendments,[4] federal due process and equal protection were deemed to require only fundamental fairness in state procedures rather than to embody specific guarantees in the same manner in which they were written in the Bill of Rights. In the familiar *Slaughter-House Cases*,[5] the Supreme Court held that the fourteenth amendment did not add to the rights, privileges, or immunities of the citizens of the several states. Eleven years later in *Hurtado v. California*,[6] the Court declared that "[d]ue process of law" referred to "that law of the land in each State, which derives its authority from the inherent and reserved powers of the State."[7]

Even in the twentieth century, the Court held that the fourteenth amendment did not impose on states the obligation to recognize the right against self-incrimination contained in the fifth amendment.[8] And it was not until 1925 that the Court held that the first amendment limited a state's regulation of free speech and free press.[9]

This is not to say that Americans were without protection from the excesses of government. States and state courts pursued the obligations which the drafters at Philadelphia assumed they would continue to pursue: protection of the civil liberties of Americans through the use of state bills of rights.

Indiana was an early and noteworthy participant in using its bill of rights to defend personal liberty. The Indiana Supreme Court, for ex-

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3. Barron v. Baltimore, 32 U.S. (7 Pet.) 243, 247 (1833).

4. U.S. CONST. amend. XIII; U.S. CONST. amend. XIV; U.S. CONST. amend. XV.

5. 83 U.S. (16 Wall.) 36 (1872).

6. 110 U.S. 516 (1884).

7. *Id.* at 535.

8. Twining v. New Jersey, 211 U.S. 78 (1908), *implicitly overruled*, Malloy v. Hogan, 378 U.S. 1 (1964).

9. Gitlow v. New York, 268 U.S. 652 (1925).

ample, spent forty years asserting its authority in the fight against slavery. The very first volume of Blackford's Reports records the court's decision in *State v. Lasselle*,[10] an appeal by a slave known only as Polly, whose Virginia owner had been granted a writ of habeas corpus. Our supreme court reversed, observing that "the framers of our constitution intended a total and entire prohibition of slavery in this State; and we can conceive of no form of words in which that intention could have been more clearly expressed."[11]

When the legislature passed a statute making it a crime to induce the escape of a slave or to hide one, the Indiana Supreme Court invalidated the law[12] on the basis of the United States Constitution as interpreted in *Prigg v. Pennsylvania*,[13] a decision of the Taney Court affirming federal fugitive slave laws. Eventually confronted with the very federal fugitive slave laws affirmed in *Prigg*, which allowed United States marshals to take possession of slaves and return them to their owners, the Indiana Supreme Court in *Freeman v. Robinson*[14] found a slave has the right to sue the marshal in state court for assault, battery and extortion. These are not part of the marshal's duty, the court held, implicitly concluding that charging Freeman three dollars a day for his keep might be fairly called extortion.[15] Because Congress has not legislated on these matters, Judge Gookins wrote for the court, "[W]e do not see that it is possible there should be any conflict between federal and state authorities."[16]

These were but a few in a fine line of cases in which the Indiana Supreme Court held that the Indiana Bill of Rights afforded Hoosiers rights which the federal Constitution did not. In 1825, for example, the court declared unconstitutional a law permitting the assessment of damages in condemnation cases by three appraisers, holding that article I, section 5, of the 1816 Constitution guaranteed a right to trial by jury.[17] As Judge Fisher of the Indiana Tax Court noted in July 1988, this is still not a right recognized under the seventh amendment.[18]

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10. 1 Blackf. 60 (Ind. 1820).

11. *Id.* at 62.

12. Donnell v. State, 3 Ind. 480 (1852), *overruled*, State v. Moore, 6 Ind. 436, 437 (1855).

13. 41 U.S. (16 Pet.) 539 (1842).

14. 7 Ind. 321 (1855).

15. *Id.* at 323.

16. *Id.* at 323. Nevertheless, the marshal won because Freeman sued him in the wrong jurisdiction. *Id.*

17. Armstrong v. Jackson, 1 Blackf. 374, 375-76 (Ind. 1825).

18. State Line Elevator v. State Bd. of Tax Comm'rs, 526 N.E.2d 753, 754 (Ind. T.C. 1988).

More than a century before *Gideon v. Wainwright*[19] was decided in 1963, the Indiana Supreme Court held that a criminal defendant had the right to an attorney at public expense if he could not afford to hire one on his own. Relying on section 21 of our Bill of Rights, Judge Stuart wrote:

> It is not to be thought of, in a civilized community, for a moment, that any citizen put in jeopardy of life or liberty, should be debarred of counsel because he was too poor to employ such aid. No Court could be respected, or respect itself, to sit and hear such a trial. The defence [sic] of the poor, in such cases, is a duty resting somewhere, which will be at once conceded as essential to the accused, to the Court, and to the public.[20]

In 1856, the court used Indiana's double jeopardy clause to hold that a defendant was entitled to discharge after a hung jury.[21] In an early precursor of the exclusionary rule, the Indiana Supreme Court declared that article I, section 14 of the Indiana Constitution required that any incriminating statements a party might be required to give to defend himself in a civil action could not be used against him as the basis for criminal prosecution.[22] The court adopted procedures for post-conviction proceedings by prisoners nearly seventy years before the United States Supreme Court held that such were required under due process.[23]

Indiana's use of its own constitution early in this century is equally intriguing. In 1922, the Indiana Supreme Court adopted the exclusionary rule as a way of protecting Hoosiers against unreasonable searches and seizures. Relying on sections 11 and 14 of the Indiana Bill of Rights, Judge Willoughby wrote for a unanimous court, "If the property was secured by search and seizure under the pretext of a search warrant, which was invalid for any reason, then the property so seized could not be used as evidence, against the appellant and its admission over his objection was prejudicial error."[24] Without the illegally seized evidence the conviction was based on insufficient evidence, and the court discharged the defendant.[25] These words were written nearly forty years before *Mapp v. Ohio*,[26] at a time when the exclusionary rule was so

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19. 372 U.S. 335 (1963).
20. Webb v. Baird, 6 Ind. 13, 18 (1854).
21. Miller v. State, 8 Ind. 325 (1856), *implicitly overruled*, State v. Walker, 26 Ind. 346, 352 (1866).
22. Wilkins v. Malone, 14 Ind. 153 (1860).
23. Young v. Ragen, 337 U.S. 235 (1949); Sanders v. State, 85 Ind. 318 (1882).
24. Callender v. State, 193 Ind. 91, 96, 138 N.E. 817, 818 (1922).
25. *Id.* at 99, 138 N.E. at 819.
26. 367 U.S. 643 (1961).

unpopular that Professor Wigmore was moved to call it revolutionary and against all rules of evidence theretofore pertaining to the subject.[27]

Indiana declared in 1920 that a defendant had the right to counsel at pre-trial proceedings. In *Batchelor v. State*,[28] a defendant was arrested in the middle of the night and kept in jail six days before he saw a judge. He asked several times to see a lawyer and each time the police put him off. He eventually pled guilty to murder without ever having talked to an attorney. Relying on section 13 of our Bill of Rights, the Indiana Supreme Court held that "the spirit of the provision contemplates the right of accused to consult with counsel at every stage of the proceedings"[29] and set aside Batchelor's plea of guilty to murder. The Attorney General of Indiana had argued that before setting aside the conviction the prisoner should demonstrate that he was innocent or that he should not be severely punished for his acts. The court was not impressed with this assertion that a defendant must demonstrate his innocence before being granted relief from the violation of his right to counsel: "The rights of just and upright citizens are not more sacred in the eyes of the law than the rights of the poorest and meanest citizens of the state."[30]

The Indiana Supreme Court affirmed Indiana's Bill of Rights, section 13, to hold that citizens have the right to jury trials in misdemeanors, something not provided by the sixth amendment.[31] It also held that the right to counsel extended to misdemeanors.[32]

Even in the face of extensive federal activity during the Warren Court years, the Indiana Supreme Court sometimes charted its own course when reviewing search and seizure claims under the fourth amendment and the Indiana Bill of Rights. Confronted with a case in which a trial court had authorized surgery to remove bullets as evidence from a defendant's body, the court held that doing so constituted an unrea-

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27. WIGMORE, EVIDENCE; §§ 2183, 2184 (2d ed. 1923), *cited in* Flum v. State, 193 Ind. 585, 591, 141 N.E. 353, 355 (1923). In 1923 Wigmore wrote of the development of the exclusionary rule: "the heretical influence of *Weeks v. United States* spread, and evoked a contagion of sentimentality in some of the State Courts, inducing them to break loose from long-settled fundamentals." 4 WIGMORE, EVIDENCE, § 2184 (2d ed. 1923).

28. 189 Ind. 69, 125 N.E. 773 (1920).

29. *Id.* at 76-77, 125 N.E. at 776. Justice Lairy further wrote: "The privilege of the presence of counsel upon the trial would be a poor concession to the accused if the right of consultation with such counsel prior to the trial was denied." *Id.* at 77, 125 N.E. at 776 (quoting People *ex rel.* Burgess v. Risley, 66 How. Pr. 67 (N.Y. 1883)).

30. *Id.* at 84, 125 N.E. at 778.

31. State *ex rel.* Rose v. Hoffman, 227 Ind. 256, 85 N.E.2d 486 (1949).

32. Bolkovac v. State, 229 Ind. 294, 98 N.E.2d 250 (1951) (affirming right to jury trial and right to counsel in misdemeanor cases to the same extent and under the same rules that it exists in felony trials).

sonable search.[33] The court did not consider the recent United States Supreme Court cases *Rochin v. California*[34] and *Schmerber v. California*[35] to be determinative of the issue, but rather used them for guidance in interpreting the guarantee of reasonableness in searches and seizures.

The story of the Indiana Supreme Court for most of the 1970's and 1980's, however, has been a different one. Criminal defense lawyers became accustomed to arguing virtually every criminal appellate issue in terms of the federal Constitution and the Indiana Supreme Court became swamped with direct criminal appeals mandated by article 7, section 4, of the Indiana Constitution.[36] Until recently, our attention has been diverted from the jurisprudence of the Indiana Constitution. I come to suggest that this attention may be refocused for a variety of reasons.

First, the Indiana Constitution provides a great variety of protections for citizens which are not contained in the Federal Bill of Rights. Aside from the ability to submit a claim that Indiana's provisions provide greater protection, there are a great many parts of Indiana's Bill of Rights which simply have no federal counterpart.[37]

Section 3, for example, provides flatly that no law may "interfere with the rights of conscience."[38] Section 9 affirms the rights of expression

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33. Adams v. State, 260 Ind. 663, 299 N.E.2d 834 (1973), *cert. denied*, 415 U.S. 935 (1974).

34. 342 U.S. 165 (1952).

35. 384 U.S. 757 (1966).

36. IND. CONST. art. VII, § 4. This increase in direct appeals is discussed and documented in Shepard, *Changing the Constitutional Jurisdiction of the Indiana Supreme Court: Letting a Court of Last Resort Act Like One*, 63 IND. L.J. 669, 682 n.75 (1988).

37. There are also rights enumerated in articles other than the bill of rights. The Indiana Constitution has an entire article devoted to education. IND. CONST. art. VIII. In addition, article IX sets up benevolent institutions and county farms to offer refuge to those who need assistance in caring for themselves.

38. IND. CONST. art. I, § 3. The federal Constitution addresses freedom of religion together with political freedom in the First Amendment providing simply: "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof. . . ." U.S. CONST. amend. I. The Indiana Constitution on the other hand has six distinct clauses designed to protect freedom of religion and the separation of church and state. IND. CONST. art. I, §§ 2-7.

The plain language of some provisions clearly extends beyond the federal provision. Article I, section 3, for example, reads: "No law shall, in any case whatever, control the free exercise and enjoyment of religious opinions, or interfere with the rights of conscience."

The Indiana Court of Appeals has held that IND. CONST. art. I, §§ 2 & 3 does not prohibit the Indiana State University Board of Trustees from discharging a professor who insists upon reading from The Bible at the start of each of his mathematics classes. Lynch v. Indiana State Univ. Bd. of Trustees, 177 Ind. App. 172, 378 N.E.2d 900 (1978), *cert. denied*, 441 U.S. 946 (1979). The court noted: "To allow Lynch to exercise his freedom to act, here, in reading the Bible aloud to his students would infringe upon his students'

in language much more comprehensive than the first amendment.[39] Section 12, usually thought of as a simple "due process" provision, in fact, guarantees that all courts shall be open and that every person shall have a remedy.[40] Section 17 affirms that "[o]ffenses, other than murder or

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freedom to believe as they wish." *Id.* at 180, 378 N.E.2d at 905.

In 1978, the Indiana Supreme Court affirmed a trial court finding that a statute requiring photographs on drivers licenses was unconstitutional as applied to properly certified members of the Amish and Pentecostal sects. Bureau of Motor Vehicles v. Pentecostal House of Prayer, Inc., 269 Ind. 361, 380 N.E.2d 1225 (1978). The Court decided that the notion of free exercise of religion and article I, section 2 outweighed the state's interest in regulating licensing of drivers. *Id.* at 364, 368-69, 378 N.E.2d at 1227, 1229.

39. IND. CONST. art. I, § 9. In 1929, Professor Hugh E. Willis claimed that "since the United States Constitution protects [freedom of speech and of the press] against both the action of Congress and the action of state legislatures, the guaranties of state constitutions are superfluous." Willis, *Freedom of Speech and of the Press*, 4 IND. L.J. 445, 446 (1929). That this is not true is easily demonstrated by comparing differences in the text of the federal provision and some state provisions.

The first amendment's guarantee of political freedom provides that "Congress shall make no law . . . abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the government for a redress of grievances." U.S. CONST. amend. I. The Indiana Constitution provides "No law shall be passed, restraining the free interchange of thought and opinion, or restricting the right to speak, write, or print, freely, on any subject whatever: but for the abuse of that right, every person shall be responsible." IND. CONST. art. I, § 9. The Washington State Declaration of Rights, which was largely modeled after the Indiana Bill of Rights, used an even broader provision which eliminated the need for state action by providing: "Every person may freely speak, write and publish on all subjects, being responsible for the abuse of that right." WASH. CONST. art. I, § 5. *See generally* Utter & Pitler, *Presenting a State Constitutional Argument: Comment on Theory and Technique*, 20 IND. L. REV. 635, 637 (1987).

Willis' comment was not entirely without foundation, however. Indiana Supreme Court cases from the 1920's displayed a reluctance to protect the right of free speech. In Watters v. City of Indianapolis, 191 Ind. 671, 134 N.E. 482 (1922), the Indiana Supreme Court held that an ordinance prohibiting carrying any banner, placard, advertisement or handbill for the purpose of displaying it on a public street did not violate IND. CONST. art. I, § 9. The court determined that this ordinance did not deny the right of "free interchange of thought and opinion" or "the right to speak, write, or print freely" because one could still "hire a hall or print a paper." "But," the Court continued, "this does not mean that he may do as he pleases on a public street." *Id.* at 674, 134 N.E. at 483 (quoting IND. CONST. art. I, § 9). *See also* Thomas v. City of Indianapolis, 195 Ind. 440, 145 N.E. 550 (1924) (ordinance prohibiting labor picketing upheld against a challenge under IND. CONST. art. I, § 9).

41. IND. CONST. art. I, § 12. This section reads: "All courts shall be open; and every person, for injury done to him in his person, property or reputation, shall have remedy by due course of law. Justice shall be administered freely, and without purchase; completely, and without denial; speedily, and without delay."

In State *ex rel.* Board of County Comm'rs v. Laramore, 175 Ind. 478, 94 N.E. 761 (1911), the Indiana Supreme Court traced the history of this section back to the Magna

treason, shall be bailable," a guarantee easily recognized as more complete than that provided by the eighth amendment.[41] Section 19 provides that the citizens on a criminal jury shall determine for themselves both the facts and the law of the case.[42] Section 30 holds that no conviction shall work forfeiture of estate.[43] Section 31 guarantees broad rights of as-

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Charta. In upholding the constitutionality of legislation allowing sheriffs to charge a commission on sales and executions, the Court noted that this provision was not designed to abolish fixed fees to raise revenue, but rather to eliminate arbitrary, sometimes oppressive gratuities extracted to influence legal proceedings. *Id.* at 483-84, 94 N.E. 762-63. Finally, the Court indicated that the provision, though derived from the Magna Charta, "may be a broader guaranty of free, unpurchased and impartial justice . . ." and acknowledged the possibility that the constitution would be violated if "costs and fees imposed on those who resort to the courts for justice [were] so burdensome as to result in a practical denial of justice to a large number of our people." *Id.* at 485, 94 N.E. at 763.

41. IND. CONST. art. I, § 17.

42. IND. CONST. art. I, § 19. Only two other states, Georgia and Maryland, continue to have comparable provisions granting the jury the right to judge the law in criminal cases. GA. CONST. art. I, § 2-111(a); MD. DECLARATION OF RTS. art. 23. According to Mortimer and Sanford Kadish, such provisions are the only remaining "relics" of a debate on the role of the jury in English and American law which lasted from the end of the seventeenth century to the 1830s. Disagreement over the jury's role in seditious libel cases was at the center of this debate. Kadish & Kadish, *On Justified Rule Departures by Officials*, 59 CALIF. L. REV. 905, 913, 915 (1971).

The provision was discussed at the Indiana Constitutional Convention. The committee on the practice of law and law reform rejected a resolution providing that "in criminal cases the jury shall find facts alone, and the courts assess the penalty." 1 REPORT OF THE DEBATES AND PROCEEDINGS OF THE CONVENTION FOR THE REVISION OF THE CONSTITUTION OF THE STATE OF INDIANA 1850 394 (1850). According to the record of the debates, the original purpose of this section was to allow defendant's in both civil and criminal libel cases to "give the truth in evidence" as a defense. 2 *id.* at 1389.

Conflicting interpretations of this provision appeared in Williams v. State, 10 Ind. 503 (1959), just seven years after the new constitution was written.

43. IND. CONST. art. I, § 30. Historically, forfeitures were used to raise money for the king. *See* Ballard v. Board of Trustees of Police Pension Fund, 263 Ind. 79, 85-86, 324 N.E.2d 813, 817 (1975).

The constitutional provision prohibiting such forfeitures has been discussed in a number of unusual cases. In a 1957 opinion, National City Bank of Evansville v. Bledsoe, 237 Ind. 130, 144 N.E.2d 710 (1957), the court examined what happens to a tenancy by the entirety owned by a husband and wife when the husband murders the wife and then commits suicide. The court proposed a rule that tenancy by the entirety be dissolved by murder, as it is by divorce. The court found that rule did not violate IND. CONST. art. I, § 30 because "the murderer is not deprived of any property which he obtained in any other way than through the murder; he is merely prevented from enriching himself by acquiring property from the murder." *Id.* at 142, 144 N.E.2d at 716. Furthermore, the court pointed out that statutes that prevent a murderer from inheriting from his victim would be unconstitutional if they imposed a forfeiture of property as a penalty for the murder, but they have been upheld since they merely prevent the murderer from profiting by his act. *Id.*

The constitutional prohibition on forfeiture of estate has been interpreted restrictively

sembly, a right which the United States Supreme Court had to draw out of the right of free speech and free press.[44]

These and other sections clearly provide occasions when a litigant who would lose in federal court may win in state court. A clear example of such an occasion is demonstrated in a pair of cases decided in 1987 in which the Indiana Supreme Court spelled out a methodology for testing the constitutionality of a prison sentence under section 16 of our Bill of Rights, which provides: "All penalties shall be proportioned to the nature of the offense."[45] In *Taylor v. State*[46] and *Mills v. State*[47] it was quite clear that the prisoner's claims under the eighth amendment were utterly unavailing.[48] Just as clearly, both had distinctly different and stronger claims under our Bill of Rights.[49] Eventually, the court concluded that habitual offender terms for each were proportionate to their offenses, but I do not doubt that the analytical framework would compel a different conclusion under different facts.

Another such occasion occurred last winter, a full six months before the United States Supreme court's decision in *Coy v. Iowa*,[50] when our court used section 13 of Indiana's Bill of Rights to begin exploring the balance between a defendant's right to confront his accuser and the importance of protecting the child victim of molestation. The result was a new trial for Annabel Miller.[51]

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to mean a prohibition of "automatic" forfeiture to the state upon conviction. *Ballard*, 263 Ind. at 79, 324 N.E.2d at 813. The court determined that termination of benefits under the Police Pension Act as a result of the plaintiff's felony conviction was merely a fine or penalty, and did not violate the constitutional provision against forfeiture of estate. *Id.*

44. De Jonge v. Oregon, 299 U.S. 353 (1937).

45. IND. CONST. art. I, § 16.

46. 511 N.E.2d 1036 (Ind. 1987).

47. 512 N.E.2d 846 (Ind. 1987).

48. *See* Solem v. Helm, 463 U.S. 277 (1983); Rummel v. Estelle, 445 U.S. 263 (1980) Although these cases undertook a proportionality test, the Indiana Supreme Court concluded that these cases did not require the extensive proportionality test required by the Indiana Constitution.

49. "Although the United States Constitution does not require an extensive proportionality review in this case, the Indiana Constitution does require such analysis." *Mills*, 512 N.E.2d at 848.

50. 108 S. Ct. 2798 (1988) (The Supreme Court held in this case that the Confrontation Clause of the federal Constitution provides a criminal defendant in a child molestation case the right to "confront" face-to-face the witnesses giving evidence against him at trial.).

51. Miller v. State, 517 N.E.2d 64 (Ind. 1987). "The confrontation rights granted by the Indiana Constitution and the federal Constitution may differ to some degree. The Indiana clause requires 'face to face' confrontation, while the federal clause mandates only a general right 'to be confronted with the witnesses.'" *Id.* at 71.

In 1988, the Indiana Supreme Court tested the rights of victims of crime, particularly of drunk driving, to seek punitive damages against those who have caused them injury. We reviewed the 130-year-old rule of *Taber v. Hutson*,[52] concluding that the statute allowing such damages was not a violation of Indiana's double jeopardy clause.[53]

These cases on our Bill of Rights must be viewed in context with other landmark cases in 1987 and 1988 in which the court used the Indiana Constitution as the basis for resolving questions ranging from the ownership of a $1.7 million lottery ticket,[54] to the rescue of the Lake County poor relief system,[55] to the eligibility of Evan Bayh for the office of Governor.[56] Other questions the court left open for the next round of litigation, such as whether drunk driving roadblocks violate Indiana's right in section 11 against unreasonable search and seizure.[57]

The ability of our court and other Indiana courts to write good law about the Indiana Bill of Rights depends in important part upon good lawyering by those who appear before us. The Indiana Supreme Court has signaled twice this year that we will not take Indiana constitutional claims to be serious ones when litigants themselves treat them lightly.[58] In *Stroud v. State*,[59] a prisoner asked us to declare unconstitutional the use of a pen register, a device which records the number dialed on a telephone. Stroud's lawyer exhorted us to follow five other state supreme

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52. 5 Ind. 322 (1854).

53. Eddy v. McGinnis, 523 N.E.2d 737 (Ind. 1988).

54. Kaszuba v. Zientara, 506 N.E.2d 1 (Ind. 1987).

55. Lake County Council v. Dozier Allen, 524 N.E.2d 771 (Ind. 1988).

56. State Election Bd. v. Bayh, 521 N.E.2d 1313 (Ind. 1988).

57. State v. Garcia, 500 N.E.2d 158 (Ind. 1986), *cert. denied*, 107 S. Ct. 1889 (1987). "[W]hile the Court has rejected Garcia's Fourth Amendment claim, it has not so much as mentioned, much less purported to decide, the rights assured under Art. I, § 11 of the Indiana Constitution. I take it that question is to be decided another day." *Id.* at 172-73 (Shepard, J., dissenting).

58. This position is not unique to Indiana. The Utah Supreme Court requires that state constitutional issues be fully briefed with arguments for treating state provisions differently from analogous federal constitutional provisions. Justice Utter of the Washington Supreme Court describes this requirement as a "common approach." Utter, *Ensuring Principled Development of State Constitutional Law: Responsibilities for Attorneys and Courts*, 1 EMERGING ISSUES IN STATE CONSTITUTIONAL LAW 217 (1988). Utter's discussion contains two useful guidelines for practitioners making state constitutional claims: (1) analyze the state's law including its constitutional law, before reaching a federal claim; and (2) discuss what the state's guarantee means and how it applies to the case at hand, not just whether the state's guarantee is the same or broader than its federal counterpart as interpreted by the United States Supreme Court. *Id.* at 220. A basic approach to developing a state constitutional argument can be found in Collins, *Litigating State Constitutional Issues: The Government's Case*, 1 EMERGING ISSUES IN STATE CONSTITUTIONAL LAW 201 (1988).

59. 517 N.E.2d 780 (Ind. 1988).

courts in so holding, without so much as citing the section of the Indiana Bill of Rights on which he relied, much less supplying any authority. That this could be regarded as a basis for a constitutional declaration is impossible.

More recently, Barry Wayne St. John asked the Indiana Supreme Court to reverse his 20-year conviction because of a prosecutor's threats to a witness. He explained at some length why this violated the fourteenth amendment, a claim we addressed on the merits. He also said that it violated section 12 of our Bill of Rights. Period. We declared that he had waived the issue for failing to argue it.[60]

In short, our ability to make good law frequently depends on counsel, and I solicit your help.

Those who wrote the federal Constitution and the national Bill of Rights regarded state constitutions and state courts as vital in protecting the liberties of the people. They understood that putting down rights on paper hardly assured that they would be recognized by those who govern,[61] and their vision turned out to be prophetic. One could examine the Samozan constitution in Nicaragua, after all, and find a lengthy Bill of Rights,[62] but one which bore almost no relationship to the reality of what was going on in the country.[63]

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60. St. John v. State, 523 N.E.2d 1353 (Ind. 1988). Indiana courts have long refused to use the state constitution unless the issue is clearly joined. In Miller v. State, 77 Ind. App. 611, 134 N.E. 209 (1922), a father convicted of violating a compulsory school attendance law claimed he was protected by IND. CONST. art. I, § 3. Because Miller did not argue the attendance law was unconstitutional, the court concluded that the section was not germane to whether Miller was guilty of violating the statute. Similarly, in Vonnegut v. Baun, 206 Ind. 172, 188 N.E. 677 (1934), a resolution preventing children who had not been vaccinated from attending school was challenged as a violation of IND. CONST. art I, §§ 2-4 "in that it abridges religious and civil liberties and matters relating to conscience of many of the citizens . . . ." *Id.* at 179, 188 N.E. at 680 (quoting plaintiff's complaint). Remarking that "[n]either in brief nor in argument is it pointed out how the constitutional rights mentioned are infringed," the court found that the right of the state to require vaccination was not involved. *Id.*

61. James Madison discussed this problem in The Federalist Papers. He referred to the State of Pennsylvania as an example. A Council of Censors assembled there in 1783 and 1784 "to inquire whether the Constitution had been preserved inviolate in every part." They reported that "the Constitution had been flagrantly violated by the Legislature in a variety of important instances. . . . The constitutional trial by jury had been violated. . . ." THE FEDERALIST No. 48, at 276 (J. Madison) (E.H. Scott ed. 1894).

62. CONST. arts. 36-127 (Nicaragua) (1950, repealed 1974).

63. According to JOHNSON RESEARCH ASSOCIATES, AREA HANDBOOK FOR NICARAGUA 156 (1970), "Personal rights such as freedom of conscience, religion, speech, peaceful assembly, and individual liberty are guaranteed." However, the president also has the authority under articles 196 and 197 of the Nicaraguan Constitution to suspend all constitutional guarantees when the "public tranquility" is threatened. *Id.* (citations omitted).

A similar override provision can be found in the Canadian Charter of Rights and

Our constitution's founders believed that the rights of Americans could only be secured by creating a federal system full of checks and balances. They borrowed this idea from the French philosopher Montesquieu, who proposed that governmental authority be dispersed among competing institutions in order that no part of the government could achieve so much power as to have the capacity for tyranny.[64] The federal system created in 1787 supposes two kinds of dispersion of power. One is vertical, what we call separation of powers: legislative, judicial, and executive. The other is horizontal, between state governments and the national government.

The rights of Americans cannot be secure if they are protected only by courts or only by one court. Civil liberties protected only by a U.S. Supreme Court are only as secure as the Warren Court or the Rehnquist Court wishes to make them. The protection of Americans against tyranny requires that state supreme courts and state constitutions be strong centers of authority on the rights of the people. I am determined that the Indiana Constitution and the Indiana Supreme Court be strong protectors of those rights.

Freedoms. CAN. CONST. I, § 33 reads: "Parliament or the legislature of a province may expressly declare in an Act of Parliament or of the legislature, as the case may be, that the Act or a provision included thereof shall operate notwithstanding a provision included in section 2 or sections 7 to 15 of this Charter.

64. "For the politics of his own time, Montesquieu's single most important doctrine in The Spirit of Laws was the theory that intermediary bodies, such as the nobility, the parliaments, the local courts of seigneurial justice, and the church, were all indispensable to political liberty." M. RICHTER, THE POLITICAL THEORY OF MONTESQUIEU 103 (1977).

An Indiana Doctor's Duty to Warn Non-Patients at Risk of HIV Infection from an AIDS Patient

KENNETH M. STROUD*

I. INTRODUCTION

Acquired Immune Deficiency Syndrome, commonly known as AIDS, is one of the major health problems in the United States. The reason is easy to understand if one looks at the now conventional medical model for AIDS.

1. AIDS is a fatal disease in which the body's immune system is rendered incapable of fighting certain unusual diseases and malignancies which cause the death of the patient.[1]
2. The disease of AIDS is caused by an unusual virus known as the AIDS virus or Human Immunodeficiency Virus (HIV) which attacks the body's immune system rendering it incapable of fighting the deadly diseases.[2] Over a period of years, this

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1. REPORT OF THE PRESIDENTIAL COMMISSION ON THE HUMAN IMMUNODEFICIENCY VIRUS EPIDEMIC 7-10 (June 24, 1988) [hereinafter PRESIDENTIAL REPORT]; "Approximately 10% of HIV-infected persons with symptoms diagnostic of AIDS do live for at least five years." *Id.* at 8; *see also* SURGEON GENERAL'S REPORT ON ACQUIRED IMMUNE DEFICIENCY SYNDROME 9-10 (1987) [hereinafter SURGEON GENERAL'S REPORT]; W. CURRAN, L. GOSTIN & M. CLARK, AIDS: LEGAL AND REGULATORY POLICY 221-233 (1988) [hereinafter CURRAN]. *Revision of the CDC Surveillance Case Definition for Acquired Immunodeficiency Syndrome*, 36 MORBIDITY & MORTALITY WEEKLY REP. Supp. 1, 3S-15S (1987) [hereinafter *CDC Revision*] contains the definition of AIDS by the Center for Disease Control for reporting purposes. As of February 20, 1989, in the United States there were 87,188 cases of AIDS reported to the Center for Disease Control and 49,976 deaths. Telephone interview with Surveillance and Evaluation Branch, U.S. AIDS Program, Center for Infectious Diseases, Center for Disease Control (Feb. 20, 1989). As of January 31, 1989, 451 cases and 236 deaths from AIDS were reported in Indiana. INDIANA STATE BOARD OF HEALTH INDIANA MONTHLY AIDS SUMMARY (Feb. 1, 1989). The SURGEON GENERAL'S REPORT, *supra*, at 6, estimates that by the end of 1991 there will have been 270,000 cases of AIDS in the United States.

2. PRESIDENTIAL REPORT, *supra* note 1, at 2, 7-10; *see also* SURGEON GENERAL'S REPORT, *supra* note 1, at 9-10; CURRAN, *supra* note 1, at 221-26; R. Gallo & L. Montagnier, *AIDS in 1988*, SCIENTIFIC AMERICAN, Oct. 1988, at 40. This virus has been known in the scientific community by different names, *e.g.*, HTLV-III (Human T Lymphotropic Virus Type III) and LAV (Lymphodenopathy Associated Virus). By international agreement HIV

virus will likely cause the infected person to develop AIDS.[3] AIDS itself is the end-stage of the HIV infection and earlier stages may be without any signs of illness.[4]

3. Once the virus infects a person it becomes a permanent part of that person's body fluids, *e.g.*, blood, semen, breast milk, urine, saliva, tears, vaginal fluid, etc.[5]
4. The virus is transmissible to other people through the transfer of infected body fluids into the body of another. Theoretically, the virus can be transmitted through any of those body fluids, however, it is firmly believed that it cannot be transmitted by casual contact.[6] The documented cases of transmission in adults have all involved semen (sexual intercourse), and blood (blood transfusions, blood splashes, needle sticks or IV needle sharing).[7]
5. The infected person may be completely without symptoms and unaware of his or her infection. Thus, that person would be unaware that the virus is being transmitted to others.[8]
6. Currently there is no cure or vaccine for the infection or for AIDS itself.[9]

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is now the accepted designation. *CDC Revision*, *supra* note 1, at 15S. It is also accepted that there are two distinct viruses, HIV-1 and HIV-2. The CDC initiated surveillance for HIV-2 in the United States in January 1987 and so far its prevalence is near zero. *AIDS Due to HIV-2 Infection-New Jersey*, 37 MORBIDITY & MORTALITY WEEKLY REP. 33 (1988). It is estimated that by the end of 1991 there will be 1.5 million persons infected with HIV in the United States. *Quarterly Report to the Domestic Policy Council on the Prevalence and Rate of Spread of HIV and AIDS-United States*, 37 MORBIDITY & MORTALITY WEEKLY REP. 551 (1988); *see also* PRESIDENTIAL REPORT, *supra* note 1, at 3.

3. PRESIDENTIAL REPORT, *supra* note 1, at 8: "Although current data shows that approximately thirty-five percent of infected persons will develop AIDS within six years, some believe that with time it may approach 100 percent."

4. PRESIDENTIAL REPORT, *supra* note 1, at 7-8.

5. CURRAN, *supra* note 1, at 228. *See also Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitus B Virus, and Other Bloodborne Pathogens in Health-Care Settings*, 37 MORBIDITY & MORTALITY WEEKLY REP. 377 (1988) [hereinafter *Update*].

6. M. Sande, *Transmission of AIDS: The Case Against Casual Contagion*, 314 NEW ENG. J. MED. 380 (1986); *see also* T. Peterman & J. Curran, *Sexual Transmission of Human Immunodeficiency Virus*, 256 JAMA 2222 (1986).

7. CURRAN, *supra* note 1, at 228-30; *see also* W. Heyward & J. Curran, *The Epidemiology of AIDS in the U.S.*, SCIENTIFIC AMERICAN, Oct. 1988, at 72; *Update*, *supra* note 5, at 377.

8. PRESIDENTIAL REPORT, *supra* note 1, at 7; *see also* SURGEON GENERAL'S REPORT, *supra* note 1, at 10-11; CURRAN, *supra* note 1, at 232-33.

9. PRESIDENTIAL REPORT, *supra* note 1, at 47-49; *see also* SURGEON GENERAL'S REPORT, *supra* note 1, at 10; CURRAN, *supra* note 1, at 221; Francis & Petricciani, *The Prospects For and Pathways Toward a Vaccine for AIDS*, 313 NEW ENG. J. MED. 1586-

This picture of the virus is enough to make it one of the most feared organisms known to medicine, with a concomitant tendency to produce great anxiety in ordinary people. This anxiety is accentuated by the fact that most AIDS patients are homosexual men and/or IV needle-sharing drug abusers.[10] This fact has added another dimension to the stigma already attached to HIV infection as a deadly, contagious disease.

This type of communicable disease raises numerous legal and political problems for society. The key to understanding and dealing with these problems is to recognize the tension between two powerful social imperatives.

The first is the need to prevent the spread of the AIDS virus. The description of the nature of the virus can be seen as a recipe for social castastrophe unless checked. If the virus continues to spread it could put intolerable strains on our society's fundamental shared values of compassion for the sick, and individual freedom. The second imperative is to protect those persons known to be infected from social devastation. Many people will have a desire to know who is infected with the virus in order to take what they consider appropriate preventive action. Employers, insurance companies, landlords, hospitals, prisons, schools, blood banks, and neighbors may all try to claim some interest in knowing the HIV infection status of any given person. The problem is that when that status becomes known, the victims may be threatened with devastating reactions, such as loss of jobs, insurance, medical treatment, housing, family and friends. Resolving the conflict between these imperatives in specific areas in effective and humane ways is vital to the preservation of the social fabric.

The challenge to the legal system is to determine whose demands to know whether a person is infected outweigh the privacy interests of the infected person and what actions are appropriate based on that knowledge. This is an old problem—balancing the privacy interests of the infected person with the public health interests in protecting the public and curing the victim—in a new guise.[11] The urgency stems from the nature of this peculiar virus.

One aspect of that problem can be put this way: what is the duty of one who knows another person is infected with HIV? Does he serve the strong interests in privacy and not reveal his knowledge or does he

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90 (1985); Yarchoan, Mitsuya & Broder, *AIDS Therapies*, Scientific American, Oct. 1988, at 110; Matthews & Bolognesi, *AIDS Vaccines*, Scientific American, Oct. 1988, at 120.

10. Surgeon General's Report, *supra* note 1, at 15, 19; 37 Morbidity & Mortality Weekly Rep. 290 (1988).

11. Jacobson v. Massachusetts, 197 U.S. 11 (1905) (compulsory vaccination).

serve the equally strong interests in prevention by warning those endangered by the infected person? This Article concerns one sub-part of that problem, namely, the case of the ordinary Indiana physician[12] who determines that one of his patients is infected with the virus. How is the doctor to determine whether he has a duty to warn non-patients who may be at risk of infection by the patient?

Traditionally the doctor's knowledge about the patient obtained through examination and disclosure by the patient is to be kept confidential to protect the privacy interests of the patient. On the other hand, the duty of confidentiality has never been held to be an absolute value and the problem is in specifying the circumstances under which the doctor must breach the duty of patient confidentiality.[13] This Article approaches this question by analyzing the factors an Indiana doctor must consider to determine whether he has a duty to breach the patient's privacy and warn a non-patient who has been or will be exposed to infection with the AIDS virus by the patient.

II. Doctor's Duty of Confidentiality Concerning The Medical Status of A Patient

The policy underlying the intuitively grasped need for a rule of confidentiality[14] is two-fold: (1) to protect the patient's privacy, *i.e.*, prevent revelations of the patient's medical condition which would subject the patient to humiliation and social stigma, and (2) to induce the full disclosure from the patient that is required for effective diagnosis and treatment by the doctor. The confidential nature of the doctor-patient relationship is generally taken for granted by doctor and patient alike. However, it has a patchy legal basis, its scope is unclear and the sanction for its breach varies.

A. Standards of Professional Conduct

In Indiana the standards of professional conduct for physicians are embodied in regulations adopted and enforced by a legislatively created

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12. Ind. Code § 25-22.5-1-1.1(g) (1988) states: "'Physician' means any person who holds the degree of doctor of medicine or doctor of osteopathy or its equivalent and who holds a valid unlimited license to practice medicine or osteopathic medicine in Indiana."

13. Closen & Isaacman, *The Duty To Notify Private Third Parties of the Risks of HIV Infection*, 21 J. Health and Hosp. Law 295 (1988); Dickens, *Legal Limits of AIDS Confidentiality*, 259 JAMA 3449 (1988); Comment, *Doctor-Patient Confidentiality Versus Duty To Warn in the Context of AIDS Patients and Their Partners*, 47 Md. L. Rev. 675 (1988); Comment, *The Physician's Duty To Warn Non-Patients: AIDS Enters the Equation* 5 Cooley L. Rev. 353 (1988); Note, *Between a Rock and a Hard Place: AIDS and the Conflicting Physician's Duties of Preventing Disease Transmission and Safeguarding Confidentiality*, 76 Geo. L.J. 169 (1987).

14. Collins v. Bair, 256 Ind 230, 268 N.E.2d 95 (1971); *see also* 12 R. Miller, Indiana Practice, Indiana Evidence § 504.101, at 391 (1984).

state agency, the Medical Licensing Board.[15] The sanctions for violation of these standards could be as severe as permanent revocation of the physician's license to practice.[16] The standard concerning confidentiality states:

> A practitioner shall maintain the confidentiality of all knowledge and information regarding a patient, including, but not limited to, the patient's diagnosis, treatment and prognosis, and all records relating thereto, about which the practitioner may learn or otherwise be informed during the course of, or as a result of, the patient-practitioner relationship. Information about a patient shall be disclosed by a practitioner when required by law . . . .[17]

This standard makes clear that an Indiana doctor owes an enforceable duty to his patients to keep their medical status confidential. This regulation is applicable to all Indiana physicians, and the possible sanctions for violation and attendant publicity must be assumed to be significant enough to cause each one to take this duty seriously. However, there are no court cases interpreting this regulation nor any published opinions or judgments of the Board on the subject. Therefore, neither the scope of the duty nor when the disclosure will be deemed "required by the law," are known.[18]

B. Civil Damage Suits For Breach

There are also no Indiana cases deciding whether the doctor's breach of this duty is compensable in a civil suit for damages. However, it is

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15. IND. CODE section 25-22.5-2-1 (1988) creates the Medical Licensing Board and section 25-22.5-2-7(8) empowers the Board to "[a]dopt rules establishing standards for the competent practice of medicine, osteopathic medicine, or any other form of practice regulated by a limited license or permit issued under this article."

16. IND. ADMIN. CODE tit. 844, r. 5-1-3 (1988) provides:

> Failure to comply with the above standards of professional conduct and competent practice of medicine may result in disciplinary proceedings against the offending practitioners. Further, all practitioners licensed in Indiana shall be responsible for having knowledge of the standards of conduct and practice established by statute and regulation pursuant to Ind. Code section 25-22.5-2-7.

The Board is also given the power to impose sanctions. *See* IND. CODE § 25-1-9-4(a) (1988). That section provides:

> A practitioner shall conduct the practitioner's practice in accordance with the standards established by the board regulating the profession in question and is subject to the exercise of the disciplinary sanctions under Section 9 of this chapter if, after a hearing, the board finds: . . . (3) A practitioner has knowingly violated any state statute or rule . . . regulating the profession in question.

IND. CODE section 25-1-9-9 sets out the allowable sanctions which range from a letter of reprimand to permanent revocation of the license.

17. IND. ADMIN. CODE tit. 844, r. 5-1-2(a) (1988).

18. *Id.*

clear that the Indiana Supreme Court could recognize such a remedy because this issue has been decided in several other jurisdictions with most of the courts finding that damages are awardable against the doctor for breach of the duty.[19] In deciding the question, those courts identified several expressions of public policy supporting a duty of confidentiality which permitted the recognition of a civil action for damages for breach of that duty.

One of the most common factors considered by the courts is the existence of licensing regulations which create disciplinary sanctions for breach of professional conduct, including the duty of confidentiality.[20] As noted above, Indiana has such a regulation binding its doctors.

A second significant factor is the ethical requirement of the profession as expressed in the American Medical Association's Principles of Medical Ethics, Principle No. IV:

> A physician shall respect the rights of patients, of colleagues, and of other health professionals, and shall safeguard patient confidences within the constraints of the law.[21]

This code is not binding on any non-member doctors. However, it does serve to remind all doctors of the fundamental value of confidentiality even though there is no way to determine the scope of the duty without knowing the scope of the exception "within the constraints of the law."[22]

Another expression of ethical self-understanding by the medical profession is the Hippocratic Oath. This ancient oath states:

> Whatever in connection with my professional practice, or not in connection with it, I see or hear, in the life of men, which ought not be spoken of abroad, I will not divulge, as reckoning that all such should be kept secret.[23]

However, it is not known whether this oath is ever actually read and/or taken by a doctor.[24] The Indiana University Medical School does not

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19. *See* cases cited *infra* notes 20, 34, 37.

20. *See* Horne v. Patton, 291 Ala. 701, 287 So. 2d 824 (1974); Hammonds v. Aetna Casualty & Sur. Co., 243 F. Supp. 793 (N.D. Ohio 1965); Simonsen v. Swenson, 104 Neb. 224, 177 N.W. 831 (1920).

21. American Medical Ass'n, *Principles of Medical Ethics, No. IV* (1980).

22. *Id.*

23. J. Areen, P. King, S. Goldberg & A. Capron, Law, Science and Medicine 273 (1984).

24. *See* M. Etziony, The Physician's Creed (1973). The author reports a survey conducted by the British Medical Association to determine whether the British medical schools required such an oath. The survey found "there is no place of medical education in the British Isles at which the Hippocratic Oath is taken in the form popularly supposed. At a number of universities, however, the tradition of a formal oath-taking ceremony is in one way or another maintained." *Id.* at 146.

require the taking of the Hippocratic Oath before graduation.[25] However, it does have the graduate take an oath which includes the following provision: "I will respect the secrets which are confided in me."[26] The Medical Licensing Board does not require any oath as a prerequisite to the practice of medicine in Indiana.[27]

The last expression of public policy considered in these cases is the Doctor-Patient testimonial privilege which allows the patient to prevent the doctor from breaching patient confidentiality in a legal proceeding. Indiana has a statute[28] which the courts interpret to mean that a physician as a witness at a legal proceeding cannot be permitted or compelled to divulge, over the objection of his patient, medical information about the patient acquired in the course of his professional duty.[29] This rule allows the courts to determine the scope of the relationship, the definition of a patient waiver and definition of certain exceptions allowing the doctor to divulge the information without violating his duty of confidentiality. Although there are no Indiana cases on point, it is generally held that this evidentiary rule prevents the doctor from giving certain *testimony* but does not, by itself, create an enforceable duty to maintain confidentiality in extra-judicial situations where the doctor is not giving evidence as a witness.[30] Some courts have held that the existence of this testimonial privilege is a legislative expression of the social value of such confidentiality and that this expression of public policy can be relied upon to create a civil action for damages for its breach extra-judicially.[31]

With these manifestations of public policy available, Indiana courts could follow several other jurisdictions and create a civil remedy in damages for breach of the duty of confidentiality. Recovery has been predicated upon a theory of implied contract. In *Hammonds v. Aetna Casualty*,[32] the court held:

> Any time a doctor undertakes the treatment of a patient, and the consensual relationship of physician and patient is established, two jural obligations (of significance here) are si-

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25. Private communication with Mr. John Ficklin, Assistant Dean for Student and Curricular Affairs, Indiana University Medical School (Jan. 1989).

26. M. Etziony, *supra* note 24, at 88-89. This oath is the *Declaration of Geneva*, adopted by the General Assembly of the World Medical Association in Geneva, September 1948.

27. Ind. Code § 25-22.5-3-1 (1988) (no oath is required for licensing).

28. Ind. Code § 34-1-14-5 (1988).

29. R. Miller, *supra* note 14, at 391. *See also* Collins v. Blair, 268 N.E.2d 95 (Ind. 1971).

30. R. Miller, *supra* note 14, at 404-06.

31. *See* cases cited *supra* note 20.

32. 243 F. Supp. 793 (N.D. Ohio 1965).

> multaneously assured by the doctor. Doctor and patient enter into a simple contract, the patient hoping that he will be cured and the doctor optimistically assuming that he will be compensated. As an implied condition of that contract, this Court is of the opinion that the doctor warrants that any confidential information gained through the relationship will not be released without the patient's permission.[33]

If the recovery were limited to an action for breach of contract, however, the patient would generally be limited to economic loss flowing directly from the breach and would thus be precluded from recovering for emotional distress, loss of employment and the deterioration of certain relationships.[34] This limitation in remedy has caused several courts to rely upon tort, rather than contract remedies for the breach of the duty. In *MacDonald v. Clinger*[35] the court wrote:

> We believe that the relationship contemplates an additional duty springing from but extraneous to the contract and that the breach of such duty is actionable as a tort . . . .
> The relationship of the parties here was one of trust and confidence out of which sprang a duty not to disclose. Defendant's breach was not merely a broken contractual promise but a violation of a fiduciary responsibility to plaintiff implicit in and essential to the doctor-patient relation.[36]

Other tort theories that have been relied on are that the doctor's disclosure of confidential information was an invasion of privacy against the patient,[37] that it was a violation of public policy protecting confidentiality[38] and that the licensing statute itself created a duty enforceable in a tort action against the doctor.[39] In Indiana, such a suit by a patient against his doctor for breach of the duty of confidentiality would probably be one for malpractice. The Malpractice Statute provides, in part:

> "Malpractice" means any tort or breach of contract based on health care or professional services rendered, or which should

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33. *Id.* at 801.
34. MacDonald v. Clinger 84 A.D.2d 482, 446 N.Y.S.2d 801 (1982).
35. *Id.*
36. *Id.* at 804.
37. *See, e.g.*, Horne v. Patton, 291 Ala. 701, 287 So. 2d 824 (1974); Tower v. Hirschorn, 397 Mass. 581, 492 N.E.2d 728 (1986); Logan v. District of Columbia, 447 F. Supp. 1328 (D.C. 1978).
38. *See, e.g.*, Humphers v. First Interstate Bank of Oregon, 298 Or. 706, 696 P.2d 527 (1985); Alberts v. Devine, 395 Mass. 59, 479 N.E.2d 113 (1985).
39. Simonsen v. Swenson, 104 Neb. 224, 177 N.W. 831 (1920).

> have been rendered, by a health care provider, to a patient. . . . "Health Care" means any act or treatment performed or furnished, or which should have been performed or furnished, by any health care provider for, to, or on behalf of a patient during the patient's medical care, treatment, or confinement.[40]

Although there are no cases concerning a suit for breach of the duty of confidentiality it would seem to fit within the statute as a tort based on health care, that is, on the act of remaining silent which should have been performed by the doctor for the patient. The courts have construed the statute very broadly to cover almost any conceivable case of a patient against his doctor for a harm arising out of the provision of health care.[41]

III. Duty to Warn Non-Patients Endangered by a Patient

The duty of confidentiality is not an absolute rule but allows for exceptions in certain cases. The Indiana standard of professional conduct on confidentiality provides that "[i]nformation about a patient shall be disclosed by a practitioner when required by law."[42] The civil damage cases from other jurisdictions all recognize that there are exceptions to the duty which allow and even require the disclosure by the doctor of medical information about the patient.[43]

The question here is whether one of the exceptions exists in Indiana for the doctor who knows that his patient is HIV infected, that a non-patient has been or will be exposed to the risk of infection from the patient and that the doctor could possibly prevent the spread of the infection by disclosing to the non-patient that the patient is HIV infected. In other words, does the doctor have an enforceable duty to warn the non-patient of the patient's HIV infection? There are no cases in the United States on this precise issue. In Indiana, neither the legislature, the Medical Licensing Board nor the courts have considered it. However, other states have considered it in the context of tort suits for breach of a duty to warn non-patients about a patient with some other infectious disease or who is dangerously violent.

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40. Ind. Code § 16-9.5-1-1 (h) & (i) (1988).

41. *See, e.g.*, Ogle v. St. John's Hickey Mem. Hosp., 473 N.E.2d 1055, 1057 (Ind. Ct. App. 1985) ("Those seeking to avoid coverage under the Act travel a rocky road. The framers of the Act used *broad* language.") (emphasis in original); Scruby v. Waugh, 476 N.E.2d 533 (Ind. Ct. App. 1985) (action against physician for wrongful commitment to a mental hospital).

42. Ind. Admin. Code tit. 844, r. 5-1-2(a) (1988).

43. *See* cases cited *supra* notes 20, 34.

A. Civil Damage Suits for Breach

As a general rule, a person has no enforceable duty to come to the aid of an imperiled stranger, whose situation the person did not create.[44] When the avoidance of foreseeable harm to *P* required another person *D*, to warn *P* of such harm, the common law traditionally imposed liability for failure to warn only if *D* bore some special relationship to the threatened person.[45] Indiana follows the traditional common law rule. In *Neal v. Home Builders, Inc.*,[46] the supreme court observed: "The duty to exercise care for the safety of another arises as a matter of law out of some relation existing between the parties, and it is the province of the court to determine whether such a relation gives rise to such duty."[47] More specifically, in *Ember v. B.F.D., Inc.*,[48] the court of appeals stated:

> Negligence actions may be premised on the imposition of a legal duty to aid one in peril. . . . Normally there is no legal duty to come to the aid of a stranger. The imposition of a legal duty to aid or protect another person is dependent upon the existence of a special relationship.[49]

In the doctor-patient situation, the doctor clearly has such a special relationship with the patient and thus owes a duty of care to the patient. Just as clearly the doctor generally has no duty of care to non-patient

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44. W. Prosser & W. Keeton, Prosser and Keeton on Torts § 56, 375 (5th ed. 1984); *see also* Restatement (Second) of Torts § 314 ("The fact that the actor realizes or should realize that action on his part is necessary for another's aid or protection does not of itself impose upon him a duty to take such action."). For an excellent discussion of this rule, see Leonard, *The Good Samaritan Rule as a Procedural Control Device: Is It Worth Saving?*, 19 U.C. Davis L. Rev. 807 (1986).

45. Leonard, *supra* note 44, at 824. The Restatement (Second) of Torts § 314A provides:

> (1) A common carrier is under a duty to its passengers to take reasonable action
> (a) to protect them against unreasonable risk of physical harm, and
> (b) to give them first aid after it knows or has reason to know that they are ill or injured, and to care for them until they can be cared for by others.
> (2) An innkeeper is under a similar duty to his guests.
> (3) A possessor of land who holds it open to the public is under a similar duty to members of the public who enter in response to his invitation.
> (4) One who is required by law to take or who voluntarily takes the custody of another under circumstances such as to deprive the other of his normal opportunities for protection is under a similar duty to the other.

46. 111 N.E.2d 280 (Ind. 1953).

47. *Id.* at 285.

48. 490 N.E.2d 764 (Ind. Ct. App. 1986).

49. *Id.* at 768-69.

strangers because he has no special relationship to them, even though the doctor could, by an affirmative act, prevent harm to them by another.

1. Contagious Disease Cases.—Several jurisdictions have held that a doctor who knew or should have known that his patient had a contagious disease had a duty to warn non-patient third parties who were at risk of catching the disease from the patient. In *Wojcik v. Aluminum Co. of America*,[50] the court held that a wife could recover from her husband's employer, whose doctors had taken X-rays of the husband which showed he had tuberculosis, for not advising her of her risk of infection from her husband. The court wrote:

> It is common knowledge that tuberculosis is a contagious and communicable disease. The risk of the plaintiff-wife contracting tuberculosis from her husband, when unaware that he was so afflicted, was reasonably forseeable by the defendant. Such a risk is within the range of probability and apprehension of an ordinarily prudent person. The defendant's negligent conduct toward the plaintiff-husband under the circumstances was negligence to the plaintiff-wife.[51]

Again in *Hoffmann v. Blackmon*,[52] a Florida court held that a doctor's failure to warn a husband of his disease constituted negligence to the wife. The court noted:

> It is recognized that once a contagious disease [tuberculosis] is known to exist a duty arises on the part of the physician to use reasonable care to advise and warn members of the patient's immediate family of the existence and dangers of the disease. . . . The duty is not negated by the physician negligently failing to become aware of the presence of such a contagious disease.[53]

Courts have also found a duty to warn in cases involving smallpox,[54] typhoid[55] and syphillis.[56]

There are other contagious disease cases discussing the doctor's failure to warn. However, those cases are not precisely on point because the doctors had affirmatively told the third party that there was no danger of infection from the patient when that was not true.[57] The doctor's

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50. 18 Misc. 2d 740, 183 N.Y.S.2d 351 (1959).
51. *Id.* at 357-58.
52. 241 So. 2d 752 (Fla. Dist. Ct. App. 1970).
53. *Id.* at 753.
54. Jones v. Stanko, 118 Ohio St. 147, 160 N.E. 456 (1928).
55. Davis v. Rodman, 147 Ark. 385, 227 S.W. 612 (1921).
56. Simonsen v. Swenson, 104 Neb. 224, 177 N.W. 831 (1920).
57. *See, e.g.*, Edwards v. Lamb, 69 N.H. 599, 45 A. 480 (1899) (septic poison from a wound); Skillings v. Allen, 143 Minn. 323, 173 N.W. 663 (1919) (scarlet fever).

negligence in diagnosing the nature of the patient's illness when coupled with his undertaking to advise the third parties as to their risk made him negligent in giving that advice. When the doctor undertakes to give advice to non-patients as to their risk of infection from his patient, the relationship supporting the imposition of the duty is established and it is clear that he must use ordinary care in giving that advice. Affirmative acts by a doctor, although ones he had no duty to undertake in the first place, must always be made with reasonable care on the doctor's part. Although those cases are not the same as cases where the doctor is held to have a duty to warn a non-patient stranger, the courts did assume that such a duty to warn existed.

The courts have also been alert to the problem of determining to whom the duty is owed. In *Gammill v. United States*,[58] a case involving hepatitis, the court held that the doctor did not owe this duty to a family he did not know. The court found:

> A physician may be found liable for failing to warn a patient's *family*, *treating attendants*, or other *persons* likely to be exposed to the patient, of the nature of the disease and the danger of exposure. . . . We note the limited persons to whom such a duty is owed, again suggesting the necessity of some special relationship between the physician and those to be warned. It would appear that at the bare minimum the physician must be aware of the specific risks to specific persons before a duty to warn exists.[59]

In *Derrick v. Ontario Community Hospital*,[60] the California Court of Appeals also held that the doctor's failure to warn the plaintiffs of the patient's contagious disease was not a breach of duty to the plaintiff saying:

> It would impose an intolerable burden upon [a] [h]ospital to notify all members of the public that one of its patients being released from the hospital is suffering from a contagious, communicable disease. We can think of no way in which [a] [h]ospital could discharge such a duty. We therefore decline to impose such a duty.[61]

These contagious disease cases have not elaborated the policy framework underlying the creation of the duty. Most of them simply take it

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58. 727 F.2d 950 (10th Cir. 1984).
59. *Id.* at 954 (emphasis in original).
60. 47 Cal. App. 3d 145, 120 Cal. Rptr. 566 (1975).
61. *Id.* at 571.

for granted that the existence of the contagious disease is a sufficient basis for imposing the duty to warn non-patients on the doctor. This intuition may be correct but it does not do away with the need to have a policy rationale for the duty; for only then can the scope of the duty be adjusted to fit the special circumstances presented by different types of contagious diseases. For example, influenza might not present the same problem as HIV infection. The court in *Derrick* acknowledged this problem, "[i]t should be recognized that 'duty' is not sacrosanct in itself, but only an expression of the sum total of those considerations of policy which lead the law to say that the particular plaintiff is entitled to protection."[62]

However, the only policy issue actually discussed in *Derrick* was the extent of the burden on the defendant, when there was no readily identifiable victim endangered by the patient.

2. Violent, Dangerous Patients.—Tarasoff v. Board of Regents[63] was the first case to discuss the duty a doctor may have to a non-patient endangered by one of his violent patients. In *Tarasoff*, the defendant was a psychologist employed by the University of California and, in the course of counseling an out-patient, the latter confided his intent to kill a specific young woman whom the psychologist had never met. The defendant notified the police and sought to have his patient committed. The police released the patient because he seemed rational to them and the patient was not committed. No further efforts were made to control the patient and the defendant did not notify the endangered non-patient nor her parents. The patient killed the young woman. Her parents sued the defendant psychologist for negligently failing to warn them or their daughter of the danger posed to her by the patient. This part of the suit was *not* based on the defendant's failure to control one he was in charge of, but rather, for his failure to warn the victim or her parents of the danger. The trial court dismissed the complaint for failure to state a cause of action.[64]

The California Supreme Court reversed and held that the fact that the victim was not a patient of the psychotherapist's did not relieve him of liability:

> When a therapist determines, or pursuant to the standards of his profession should determine, that his patient presents a serious danger of violence to another, he incurs an obligation to use reasonable care to protect the intended victim against such dan-

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62. *Id.*, (quoting Dillon v. Legg, 68 Cal. 2d 728, 734, 441 P.2d 912, 916, 69 Cal. Rptr. 72, 76 (1968)).

63. 17 Cal. 3d 425, 551 P.2d 334, 131 Cal. Rptr. 14 (1976).

64. *Id.* at 431, 551 P.2d at 340, 131 Cal. Rptr. at 20.

> ger. The discharge of this duty may require the therapist to take one or more of various steps, depending upon the nature of the case. Thus it may call for him to warn the intended victim or others likely to apprise the victim of the danger, to notify the police, or to take whatever other steps are reasonably necessary under the circumstances.[65]

The *Tarasoff* court recognized that imposing a duty on the psychotherapist to warn the non-patient victim in this case was a deviation from the traditional common law "duty" rule.

> Although plaintiff's pleadings assert no special relation between [the victim] and defendant therapists, they establish as between [the patient] and defendant therapists the special relation that arises between a patient and his doctor or psychotherapist. Such a relationship may support affirmative duties for the benefit of third persons.[66]

Several states have accepted the *Tarasoff* rule and have recognized a doctor's duty to warn non-patients forseeably endangered by a violent patient.[67] Subsequent California cases have emphasized that there must be a readily identifiable victim before the duty can arise.[68] Other courts have required only that the doctor reasonably foresee that the risk created by the patients' condition would endanger other members of the general public.[69] This latter approach can be taken only where the doctor could and should have exercised control over the patient and thus prevented

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65. *Id.*

66. *Id.* at 436, 131 Cal. Rptr. at 23-24, 551 P.2d at 343-44. The RESTATEMENT (SECOND) OF TORTS § 315 provides:

> There is no duty so to control the conduct of a third person as to prevent him from causing physical harm to another unless:
>
> a) a special relation exists between the actor and the third person which imposes a duty upon the actor to control the third person's conduct, or,
>
> b) the special relation exists between the actor and the other which gives to the other a right to protection.

67. *See* Jablonski v. United States, 712 F.2d 391 (9th Cir. 1983); Hedlund v. Superior Court, 34 Cal. 3d 695, 669 P.2d 41, 194 Cal. Rptr. 805 (1983); Bardoni v. Kim, 151 Mich. App. 169, 390 N.W.2d 218 (1986); McIntosh v. Milano, 168 N.J. Super. 466, 403 A.2d 500 (N.J. Super. Ct. Law Div. 1979); Peck v. Counseling Service of Addison Co., 146 Vt. 61, 499 A.2d 422 (1985); Davis v. Lhim, 124 Mich. App. 291, 335 N.W.2d 481 (1983); Note, *The Duty To Warn Third Parties: A Retrospective on* Tarasoff, 18 RUTGERS L. J. 145 (1987).

68. *See* Mavroudis v. Superior Court of San Mateo Co., 102 Cal. App. 3d 594, 162 Cal. Rptr. 724 (1980); Thompson v. County of Alameda, 27 Cal. 3rd 741, 614 P.2d 728, 167 Cal. Rptr. 70 (1980).

69. *See* Petersen v. State, 100 Wash. 2d 421, 671 P.2d 230 (1983); Lipari v. Sears, Roebuck & Co., 497 F. Supp. 185 (D.C. Neb. 1980).

the harmful act. If the issue is not the doctor's duty to exercise such control but rather his duty to warn the victim, then that victim would have to be readily identifiable by the doctor.

Distinguishable from the *Tarasoff* duty-to-warn cases are two other situations when the doctor-patient relationship may suggest affirmative duties to non-patient strangers. One is the case where the non-patient is injured because the doctor failed to warn the *patient* that his medical condition posed a risk of harm to the general public. For example, the doctor's failure to warn a bus-driver patient that his medication could cause drowsiness, would expose the doctor to liabiity for injuries to passengers sustained in a bus accident caused by the patient's drowsiness.[70] There the doctor could not have had a duty to warn the injured passengers because he had no way of ascertaining which specific persons should be warned.

The second situation exists when the doctor has custody or control over a patient and he negligently allows the patient to escape that control and injure a third party. For example, in *Mathes v. Ireland*[71] a violent man allegedly killed the plaintiff's wife. The plaintiff claimed that the mother and grandparents of the insanely violent and dangerous man with whom they lived had a duty to control his activities and to prevent him from harming others because they knew of his condition. The court held that the duty alleged depended not upon family relationships but upon the actual assumption of care and control of one known to be dangerous and the duty inures to the benefit of third parties injured by the person to be controlled.[72] Although the third party here was a stranger to the defendants, the defendents owed the third party a duty of care to control the dangerous person of whom they had taken charge. Although the plaintiff did not sue a doctor, it is clear that if a doctor had taken charge of the violent patient and then failed to use due care in controlling that patient, the doctor could be held liable on the same theory.

In both of the above situations, the doctor owed a duty to the non-patient stranger but it was not a duty to warn the person of their risk of harm from the patient. The doctor did not have a duty to warn because there was no readily identifiable victim and therefore no feasible way to discharge the duty.

Partly in response to the *Mathes* case, the Indiana Legislature adopted a statute incorporating the principle of the *Tarasoff* case. The statute provides that a doctor owes no duty to non-patients to:

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70. *See* Kaiser v. Suburban Transp. Sys., 65 Wash. 2d 461, 398 P.2d 14 (1965); Freese v. Lemmon, 210 N.W.2d 576 (Iowa 1973) (failed to warn the patient of possible seizures causing him to be unable to control his automobile).

71. 419 N.E.2d 782 (Ind. Ct. App. 1981).

72. *Id.* at 784.

> Warn or take precautions to protect from, a patient's violent behavior, unless the patient has communicated to the provider of mental health services an actual threat of physical violence or other means of harm against a *reasonably* identifiable victim or victims, or evidences conduct or makes statements indicating an imminent danger that the patient will use physical violence or use other means to cause serious personal injury or death to others.[73]

The duty to warn is, thus, confined to narrow circumstances and may be discharged by a doctor who "makes reasonable attempts to communicate the threat to the victim."[74] But the statute does create a duty to warn reasonably identifiable non-patients even though there may be no relationship or undertaking of any kind between the doctor and the non-patient. It is, therefore, compatible with the *Tarasoff* rule.

B. Policy Considerations

The infectious disease and violent patient cases and the Indiana violent patient statute create a doctor's duty to warn non-patients and demonstrate that the interests favoring confidentiality often must yield to the interests of protecting the non-patient from serious harm. The question is whether they should control the HIV infection case. Indiana

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73. IND. CODE § 34-4-12.4-1 (1987) (emphasis added).

74. IND. CODE § 34-4-12.4-3 & 4 (1987):

Sec. 3. The duty to warn of or to take reasonable precautions to provide protection from violent behavior or other serious harm arises only under the limited circumstances specified in section 2 of this chapter. The duty is discharged by a mental health service provider who takes one (1) or more of the following actions:

(1) Makes reasonable attempts to communicate the threat to the victim or victims.
(2) Makes reasonable efforts to notify a police department or other law enforcement agency having jurisdiction in the patient's or victim's place of residence.
(3) Seeks civil commitment of the patient under [IND. CODE §] 16-14-9.1.
(4) Takes steps reasonably available to such provider to prevent the patient from using physicial violence or other means of harm to others until the appropriate law enforcement agency can be summoned and takes custody of the patient.
(5) Reports the threat of physical violence or other means of harm, within a reasonable period of time after receiving knowledge of the threat, to a physician or psychologist who is designated by the employer of a mental health service provider as an individual who has the responsibility to warn under this chapter.

Sec. 4. A mental health service provider who discloses information that must be disclosed to comply with sections 2 through 3 of this chapter is immune from civil and criminal liability under Indiana statutes that protect patient privacy and confidentiality.

courts should answer yes only if the policy considerations justifying those examples also justify the recognition of a similar duty in the HIV infection case.

In *Tarasoff* the court noted, "[i]n analyzing this issue, we bear in mind that legal duties are not discoverable facts of nature, but merely conclusory expressions that, in cases of a particular type, liability should be imposed for damage done."[75] Support for this view may be found in the writings of Professor Prosser: "Duty is not sacrosanct in itself, but only an expression of the sum total of those considerations of policy which lead the law to say that the particular plaintiff is entitled to protection."[76]

There are many different expressions of the factors that need to be considered in creating a duty.[77] The relevant policy considerations in the

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75. Tarasoff v. Board of Regents, 17 Cal. 3d 425, 434, 551 P.2d 334, 342, 131 Cal. Rptr. 14, 22 (1976).

76. W. Prosser, The Law of Torts § 53 at 325-326 (4th ed. 1971).

77. The California court in *Tarasoff* found that the factors to be considered are:

> [F]orseeability of harm to the plaintiff, the degree of certainty that the plaintiff suffered injury, the closeness of the connection between the defendant's conduct and the injury suffered, the moral blame attached to the defendant's conduct, the policy of preventing future harm, the extent of the burden to the defendant and consequences to the community of imposing a duty to exercise care with resulting liability for breach, and the availability, cost and prevalence of insurance for the risk involved. 17 Cal. 3d at 434, 551 P.2d 334, 342, 131 Cal. Rptr. 14, 22 (1976).

Prosser also conceived of the creation of a duty as resting upon a multi-factor analysis: "In the decision whether or not there is a duty, many factors interplay: the hands of history, our ideas of morals and justice, the convenience of administration of the rule, and our social ideas as to where the loss should fall." Prosser, *Palsgraf Revisited*, 52 Mich. L. Rev. 1 (1953).

Prof. Leonard sets out a list of factors that should be considered by a court in determining the appropriateness of imposing a duty of care in Good Samaritan Cases: (1) forseeability of harm to the victim should defendant choose not to attempt a rescue; (2) the closeness of the causal link between defendant's failure to rescue and the victim's injury; (3) the ease with which defendant could have accomplished a rescue, and the cost to defendant of doing so; (4) the identifiability of defendant (as opposed to a possibly larger group) as a potential rescuer; (5) the moral blameworthiness of defendant under the circumstances of the case; (6) the similarity of the facts of the case to those which invoke a traditionally recognized exception; (7) the degree to which imposing a duty in this case will further the social policy of preventing future harm; and, (8) the consequences to the community of imposing a duty in this case. Leonard, *supra* note 44, at 863-64. An excellent discussion of each factor is included.

A more condensed approach is set out in Nelson by Tatum v. Commonwealth Edison Co., 124 Ill. App. 3d 655, ____, 465 N.E.2d 513, 519 (1984): "[T]he imposition and scope of a legal duty is dependent not only on the factor of forseeability . . . but involves other considerations, including the magnitude of the risk involved in defendant's conduct, the burden of requiring defendant to guard against that risk, and the consequences of placing that burden upon the defendant."

HIV infection case can be analyzed under two broad headings: (1) the social consequences of imposing the duty and (2) the burden on the doctor of doing so.

1. Social Consequences of Imposing the Duty.—The major reason to impose on a doctor the duty to warn non-patients endangered by an HIV infected patient is to prevent the spread of HIV infection *both to and by* the person who is warned. Stopping the spread of HIV infection is of great importance for two reasons. One, HIV infection may result in AIDS, a fatal disease; and two, even if the infected person were never to get AIDS, that person's HIV infection status may cause severe social devastation including loss of job, insurance, family, friends and housing resulting from the public fear of AIDS. In order for the duty to warn to contribute to disease prevention, it must be assumed that the doctor will know of the duty, discharge it, and that the warned party will take appropriate precautions against getting the infection and/or passing it to others. These assumptions need to be true sufficiently often to outweigh the costs of the duty. Due to the deadly nature of the AIDS virus, there are strong incentives for all concerned to avoid infection and to prevent its further spread.

If the duty is clearly established and enforceable most doctors are likely to learn of it through the efforts of medical associations, educational seminars, journals, the press, television and word of mouth from other doctors. Physicians are likely to discharge this duty both because it is required by law and because failure to do so may be followed by a civil damage suit with all the attendant publicity. Many doctors may discharge it because they believe such action is morally correct. Even though getting the non-patient to act to prevent his or her own infection and the infection of others may, in some cases, be difficult, that will not generally be the case. Fear of aquiring a fatal disease is a powerful stimulant to action.

The duty to warn does not rest upon the doctors ability to predict with a high degree of accuracy whether the non-patient will become infected from the patient without the warning by the doctor. In dealing with this issue, the *Tarasoff* court found, "[w]eighing the uncertain and conjectural character of the alleged damage done the patient by such a warning against the peril to the victim's life, we conclude that professional inaccuracy in predicting violence cannot negate the therapist's duty to protect the threatened victim."[78]

For purposes of deciding whether to require the warning, the crucial point is that the known means for reducing the chances of being infected,[79]

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78. *Tarasoff*, 17 Cal. 3d at 439, 551 P.2d at 346, 131 Cal. Rptr. at 26.
79. SURGEON GENERAL'S REPORT, *supra* note 1, at 17-19.

e.g., abstinence from sex or IV drugs, wearing condoms during sexual intercourse and not sharing IV drug needles, may not be known to the non-patient unless the doctor tells that person. Even if the non-patient has that general knowledge, he or she may not know that those means need to be used with the patient. Therefore, the doctor will generally have to warn the non-patient specifically about the patient in order to make an effective warning. If the non-patient has already been exposed to the virus by the patient, the non-patient may not know that both he or she and the patient could be infected and could be spreading the virus to others. All that can be said is that it is likely that in some cases, the doctor's warning will prevent someone from getting AIDS. The need to prevent the spread of the virus and the likelihood that in some cases the warning will do so is the strongest consideration in favor of creating the duty to warn.

Certain social consequences argue *against* requiring the doctor to warn the non-patient. First, the duty to warn would require the doctor to breach the patient's confidentiality as to the patient's HIV infected condition. If the patient were aware of that breach, he or she might not consult the doctor when ill, or not give full disclosure of symptoms to the doctor, thus rendering less effective the diagnosis and treatment. This could have the anamolous effect of causing *increased* harm to society from the patient who is untreated, unaware that he or she is HIV infected, and uneducated about how to prevent spreading the virus.

Second, disclosure to the third party of the patient's HIV infection could result in devastating humiliation, social stigma and various forms of discrimination for the patient. This is because nothing exists to *require* the non-patient to keep the information about the patient confidential.

These two issues were discussed in *Tarasoff* in which the court noted:

> We recognize the public interest in supporting effective treatment of mental illness and in protecting the rights of patients to privacy . . . and the consequent public importance of safe-guarding the confidential character of psychotherapeutic communication. Against this interest, however, we must weigh the public interest in safety from violent assault.[80]

The court then pointed out that the California statutory evidentiary privilege for psychotherapist, and patients required the breach of confidentiality by the psychotherapist if necessary to prevent harm to the patient or another. The court took this as an expression of policy on how to balance the two issues. The Indiana statute is an even stronger expression of a public safety policy because it is not limited to the

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80. *Tarasoff*, 17 Cal. 3d at 440, 551 P.2d at 346, 131 Cal. Rptr. at 26.

evidentiary privilege, but directly creates an enforceable duty to warn.[81]

2. Burden on the Doctor.—Imposing the duty to warn on the doctor will be a tolerable burden only if the doctor can understand the rule, determine when it is applicable and carry it out in time to prevent the harm to the non-patient. The rule could be formulated, paraphrasing the *Tarasoff* rule, as follows:

> When a doctor determines, or pursuant to the standards of his profession should determine, that his patient is HIV infected and presents a substantial risk of infecting or of having already infected a reasonably identifiable non-patient, he incurs an obligation to warn that non-patient of the danger of infection from the patient.[82]

Because the duty to warn a non-patient at risk of HIV infection from a patient is an exception to the general duty of confidentiality, it must be carried out with the least possible breach of the latter duty. As the *Tarasoff* court stated:

> The therapist's obligations to his patient require that he not disclose a confidence unless such disclosure is necessary to avert danger to others, and even then that he do so discreetly, and in a fashion that would preserve the privacy of his patient to the fullest extent compatible with the prevention of the threatened danger.[83]

The duty to warn should thus be seen as resting upon several more specific duties. The issue then becomes whether these duties are a tolerable burden on the doctor.

The duty to warn can only arise where the doctor knows, or under applicable professional standards reasonably should have determined, that the patient is infected with the AIDS virus. Only then is the patient a danger to others. Therefore, the doctor must first make an accurate diagnosis of the patient's medical condition. If the doctor thinks that HIV infection is a possibility, the most reliable method of determining that is to have the patient's blood tested for antibodies to HIV.[84] An Indiana statute provides:

> Except as provided in subsection (b), a person may not perform a screening or confirmatory test for the antibody or antigen to

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81. IND. CODE § 34-4-12.4-1 to -4 (1988).
82. *See* text accompanying *supra* notes 63-66.
83. *Tarasoff*, 17 Cal. 3d at 441, 551 P.2d at 347, 131 Cal. Rptr. at 27.
84. PRESIDENTIAL REPORT, *supra* note 1, at 73-81; CURRAN, *supra* note 1, at 226-28.

> the human immunodeficiency virus (HIV) without the consent of the individual to be tested or a representative as authorized under IC 16-8-12.[85]

The test may be performed if ordered by a physician who has the patient's consent and the "test is medically necessary to diagnose or treat the patient's condition."[86] Thus, the doctor must ask the patient for consent to the blood test for HIV antibodies and must "document whether or not the individual has consented."[87] The doctor would then have to inform the *patient* of his or her HIV infected status and to counsel the patient concerning the means by which the virus could be transmitted to other people.

The doctor has no duty to unknown persons or the general public, even though the doctor may believe the patient is going to have sex with someone and therefore may very well infect that person.[88] There is no duty on the doctor unless it is reasonably foreseeable that a readily identifiable person has been or will be at risk of HIV infection from the patient.[89] Therefore, the doctor has the duty to take reasonable steps to identify any third parties at risk of infection from the patient. To do this the doctor must answer two questions. First, what puts a third party at risk of HIV infection from the patient? Second, are any of those third parties reasonably identifiable by the doctor?

A non-patient third party could only become HIV infected from the patient by receiving into the non-patient's body some body fluid from the infected patient. In the case of adults, the only body fluids currently viewed as creating a serious risk of infection are semen and blood.[90] The medical model posits that the modes of transmission in almost all cases are sexual intercourse or IV drug abusers sharing needles.[91] The non-patients who fall into this category are those who have already been exposed to HIV infection from the patient, *e.g.*, past or current sex or needle-sharing partners, *and* those who are in danger of being exposed in the future. The reason for warning non-patients who may already have been infected by the patient is to prevent the spread of HIV by those persons who may be unaware that they are infected and infecting others.

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85. IND. CODE § 16-1-9.5-2.5(a) (1988).
86. IND. CODE § 16-1-9.5-2.5(b)(1) (1988).
87. IND. CODE § 16-1-9.5-2.5(a) (1988).
88. Leonard, *supra* note 44, at 824; *see also* text accompanying *supra* notes 43-45, 56-54.
89. *Tarasoff*, 17 Cal. 3d at 442, 551 P.2d at 347-48, 131 Cal. Rptr. at 27-28.
90. *See supra* note 7.
91. *Id.*

Are any of these non-patients reasonably identifiable by the doctor? It will depend on what the doctor should have known about the patient and the patient's relationship to others. This information can most easily be obtained at the time of taking a thorough medical history of the patient. The doctor should try to have the complete history of the patient include information about current and past sex partners or needle-sharing partners. Of course, the patient does not have to reveal this information and the question for the doctor is, how far to proceed in identifying such third parties. The phrase "reasonably identifiable" suggests a duty to take *some* affirmative steps to determine whether there are third parties at risk from the patient and it may be that merely asking the patient satisfies that duty, regardless of the answer. In *Tarasoff*, the court addressed this issue as follows:

> Defendant therapists . . . also argue that warnings must be given only in those cases in which the therapist knows the identity of the victim. We recognize that in some cases it would be unreasonable to require the therapist to interrogate his patient to discover the victim's identity, or to conduct an independent investigation. But there may also be cases in which a moment's reflection will reveal the victim's identity. The matter thus is one which depends upon the circumstances of each case, and should not be governed by any hard and fast rule.[92]

The only clear aspect of the rule is that the doctor owes no duty to the general public.[93]

Once the doctor knows of the specific non-patient, he or she has the duty to request the patient to agree to joint counseling with the non-patient. This is clearly the preferred way to accomodate the doctor's duty to patient confidentiality and the duty to warn the non-patient because there will be no breach of the duty of confidentiality where the patient consents to the doctor telling the non-patient in the context of a joint counseling session. If the patient will not agree to joint counseling the doctor must at least try to get the patient to consent to the doctor's

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92. 17 Cal. 3d at 439 n.11, 551 P.2d at 345 n.11, 131 Cal. Rptr. at 25 n.11. *See also* cases cited *supra* note 67.

93. *See* Gammill v. United States, 727 F.2d 950 (10th Cir. 1984); Derrick v. Ontario Community Hosp., 47 Cal. App. 3d 145, 120 Cal. Rptr. 566 (1975). Other cases have not required that the non-patient be an identifiable victim but only that the doctor reasonably foresee that the risk engendered by his patient's condition could endanger other persons. *See* Lipari v. Sears, Roebuck & Co., 497 F. Supp. 185 (D.C. Neb. 1980). This could only be workable for a duty to control case such as *Lipari* because, in a duty to warn case, the doctor has to contact a specific non-patient, whereas in a duty to control case the injured victim is not claiming the doctor should have contacted him or her personally.

notifying the non-patient and counseling that person about the risks of infection, modes of transmission and the means of prevention.

The real problem arises for the doctor only when the patient will not agree to allow the doctor to warn the non-patient. It may be thought that the doctor will not have to contact the non-patient over the patient's objection if the patient will inform the non-patient of the patient's HIV infection, the risk of transmission to the non-patient, means of prevention and other relevant information. If the patient could be relied upon to inform the non-patient of all the things the doctor would have mentioned, then the doctor would no longer have a duty to so warn because the purpose of such warning would be fulfilled. However, the doctor will seldom if ever have a basis for sufficient confidence that the patient will in fact, not only tell the non-patient of the patient's HIV infection, but also tell the non-patient of *the non-patient's* risk of infection, modes of transmission and means of prevention.

Another possibility is that the patient will not agree to tell the non-patient but he or she will agree to refrain from engaging in "high risk" behavior with the person, that is, stop sharing IV drug needles or having sexual intercourse only with condoms. If the patient actually followed through on promise, it would reduce the risk of infection to the non-patient, without informing the non-patient of the true situation. It is very questionable whether the doctor would satisfy his or her duty of using due care to prevent harm to the non-patient by exacting a promise from the patient that the patient will refrain from behavior that puts the non-patient at risk as this is a patient who has already refused to consent to the doctor notifying the non-patient. The doctor could rarely rely on the patient's promises in that context. Even if the doctor had confidence in the patient's willingness to carry out the promise, there is another reason to reject this solution. The fundamental value served by the duty to warn is the non-patient's autonomy. Requiring the doctor to warn the non-patient would honor that person's autonomy—that person's right to choose how much risk to take in his or her relationship with the patient. After all, the non-patient may choose to run no further risk of infection from the patient by totally severing the relationship.

If the doctor rejects the idea of relying on the patient alone to notify the non-patient of that person's risk from the patient, then the doctor has the duty to warn the non-patient himself. Of course, the warning may be unavailing because the non-patient may not choose to act to avoid infection or may not be able to so act. Without the doctor's warning the non-patient through ignorance will sometimes be helpless to avoid the harm from the patient.

The infectious disease cases, the *Tarasoff*-type cases, and the Indiana violent patient statute, whether explicitly or not, all find the balance of similar considerations favor the duty to warn. In *Tarasoff* the court found:

> In this risk-infested society we can hardly tolerate the further exposure to danger that would result from a concealed knowledge of the therapist that his patient was lethal. If the exercise of reasonable care to protect the threatened victim requires the therapist to warn the endangered party or those who can reasonably be expected to notify him, we see no sufficient societal interest that would protect and justify concealment. The containment of such risk lies in the public interest.[94]

Only a significant difference between those cases and the HIV infection case could justify a different result. The only difference which could be that significant is the potentially greater harm to the patient from the disclosure of his infection.

In most cases the harm from such disclosures will be small. The doctor is going to reveal the patient's condition only to specific, identified sex or needle-sharing partners of the patient. He or she is not disseminating the information to the general public. The non-patient might broadcast the information, but there would be little incentive to do that because it would be tantamount to admitting that the non-patient also was infected. It does not seem likely that the legislature or the courts would decline to create a duty to warn based on the evaluation that there is a significant difference in the impact on the patient of the disclosure of the patient's HIV infected condition.

IV. An Alternative to the Doctor's Duty to Warn a Non-Patient: Reporting Statutes

In the *Tarasoff* case, the duty to warn a non-patient was listed as *one* of the ways to discharge the duty of care owed to a reasonably foreseeable victim of the patient.

> When a therapist determines, or pursuant to the standards of his profession should determine, that his patient presents a serious danger of violence to another, he incurs an obligation to use reasonable care to protect the intended victim against such danger. The discharge of this duty may require the therapist to take *one or more of various steps*, depending upon the nature of the case. *Thus it may call for him to warn the intended victim or others likely to appraise (sic) the victim of the danger, to notify the police, or to take whatever other steps are reasonably necessary under the circumstances.*[95]

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94. 17 Cal. 3d at 442, 551 P.2d at 347-48, 131 Cal. Rptr. at 27-28.
95. *Id.* at 431, 551 P.2d at 340, 131 Cal. Rptr. at 20 (emphasis added).

The therapist in *Tarasoff* did attempt to have the patient committed and requested the police to pick him up for such purpose. The police picked up the patient but released him because he seemed rational to them and he promised to stay away from the victim. The director of the department of psychiatry at the hospital where the therapist worked then ordered that no further action be taken to place the patient in an emergency treatment and evaluation facility. The court held that the therapist could not be held liable for failing to confine the patient because of a statute providing immunity in such a case. However, the court went on to note that the plaintiffs

> can amend their complaints to allege that, regardless of the therapists unsuccessful attempt to confine Poddar [the patient], since they knew that Poddar was at large and dangerous, their failure to warn Tatiana [the victim] or others likely to apprise her of the danger constituted a breach of the therapists duty to exercise reasonable care to protect Tatiana.[96]

The lesson here is that the taking of some step to protect the victim, where the therapist knows that it failed, will not excuse the failure to take further, more effective steps to protect him or her.

The test for whether the therapist must warn the victim becomes whether that additional step is "reasonably necessary in the circumstances" because the first step is known to have failed. The Indiana "*Tarasoff*" statute addresses this issue by providing that the duty to "take reasonable precautions"[97] to protect a victim from a violent patient is discharged by a doctor who takes *one or more* of several steps: makes a reasonable attempt to notify the victim, makes a reasonable effort to notify the police, seeks civil commitment or takes reasonable steps to prevent the patient from harming the victim until the police arrive.[98] The statute provides that *one* or more of these steps will discharge the duty of care to the victim.[99] However the statute does not address the situation, like *Tarasoff*, where the doctor attempted to commit the patient and actually had the patient arrested, but, knowing that both of these efforts had failed, *then* did not warn the intended victim. If taking any *one* of the listed steps is intended to be *by itself* a sufficient condition for discharging the doctor's duty of care to the intended victim, regardless of whether the doctor knew it had failed, then it is a sharp departure from the *Tarasoff* case and the rule requiring what is reasonably necessary

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96. *Id.*
97. IND. CODE § 34-4-12.4-3 (1988). *See also supra* note 74.
98. *Id.*
99. *Id.*

in the circumstances. It is most likely that the Indiana courts, in interpreting the statute, would follow *Tarasoff* and require the therapist to take reasonable precautions to protect the victim in light of the therapist's knowledge about the failure of previous precautions.

The question in the HIV case is whether the doctor's duty of care to prevent harm to the non-patient can be discharged by means other than the doctor warning the non-patient of the HIV infected status of the patient. The *Tarasoff* rule held, "thus it may call for him to warn the intended victim *or others likely to apprise the victim of the danger* . . . ."[100] The obvious candidate for this alternative way to discharge the doctor's duty of care to the non-patient is the doctor's compliance with a state system for reporting HIV infection cases to the health authorities.

Indiana statutes requiring doctors to report medical information about a patient to some official agency are quite common and apply to a variety of medical problems.[101] Indiana has a statute which requires that each licensed physician "shall report to the state board each case of human immuno-deficiency virus (HIV) infection, including each confirmed case of acquired immune deficiency syndrome (AIDS)."[102]

The doctor's report on the HIV infected patient to the public health authorities could be the legal equivalent of, and therefore a substitute for, the doctor's personal warning of the endangered non-patient only if the state has a program which meets three conditions. One, the doctor's report is required to contain sufficient identification of the patient; two, some state employee has a duty to contact the patient and attempt to determine the identity of any non-patients who have been or will be exposed to the virus through the patient; and three, it is the further duty of such employee to contact each such identifiable non-patient, to warn them of their exposure to HIV infection, to counsel them about the nature of the infection and to inform them of the means to prevent the further spread of the virus.

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100. *Tarasoff*, 17 Cal. 3d at 431, 551 P.2d at 340, 131 Cal. Rptr. at 20.

101. *See* IND. CODE § 31-6-11-3 (1988) (child abuse); *id.* § 35-46-1-13 (elderly abuse); *id.* § 35-47-7-1 (firearms or knife wounds); *id.* § 35-47-7-3 (burns); *id.* § 9-11-4-6(a) (intoxication evidence); *id.* § 16-4-10-7 (birth problems).

102. *Id.* § 16-1-9.5-2(b). The State Board of Health (SBA) has implemented this statute in IND. ADMIN. CODE tit. 410, r. 1-2.1-6(b)(14) (1988):

> For purposes of reporting under these rules, physicians and hospital administrators shall report all persons with evidence of HIV infection. To clarify, the state board of health recognizes three subcategories of HIV infections:
> (a) persons who meet the CDC definition of AIDS, as found in Morbidity and Mortality Weekly Report, Vol. 36, Supplement No.1S, August 14, 1987;
> (b) persons with serologic evidence of HIV injection; and
> (c) other persons with signs/symptoms which cause the attending physician to strongly suspect HIV infection.

The advantages of relying on such a reporting and notification program under the auspices of trained employees of the public health system, instead of relying on the doctor's duty to warn the non-patients are clear. They include: reliability in contacting each reported HIV infected patient; experience in identifying the appropriate non-patients; uniformity in the information given to the non-patient; comprehensiveness in counseling the non-patient regarding the risks of infection, prevention and infecting others; relief for the doctors of the burden in time and energy of doing something that is peripheral to their main tasks (and for which they may have very little training and knowledge) and prevention of the doctor's further breach of patient confidentiality by telling the non-patient directly of the patient's HIV infection.

There are, of course, disadvantages to such a notification system. The first is the cost of the state-run system. If the doctors are required to do it, the costs might tend to be spread across many practioners and would then be negligible for any one of them, thus saving a significant amount of state funds. To the extent that the doctors with HIV infected patients are clustered in a few urban clinics, this advantage from the doctor warning system would disappear.

Second, the State Board of Health (Board) employees may be perceived as "strangers" to the parties involved and, therefore, be less successful than the doctor in talking the patient into disclosing the identity of the non-patients. Also, notification by the doctor may be perceived by the patient and the non-patient as more intimate and humane, cushioning somewhat the shock of the revelation.

Such a reporting and notification program, even with some potential disadvantages, is obviously an attractive alternative to imposing the duty to warn on the individual doctors. But both alternatives could have a problem with the reliability of the notification effort. The doctor may be negligent or simply refuse to do the warning of non-patients in spite of the possible liability for that breach of duty, and underfunding of the state system would make its efforts less reliable than is needed. The superiority of the state system rests on the assumption that there would be adequate state funding to hire the required specialists to carry out the program in a prompt, effective and reliable way.

Indiana does have a reporting and notification program with the required three components of identifying the patient, identifying the non-patients and notification of those non-patients. The Board's rules require that all doctor's reports of communicable diseases contain the patient's full name, address, telephone number, age, sex, race, date of onset, diagnosis and the name and address of the attending physician.[103] The

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103. IND. ADMIN. CODE tit. 410, r. 1-2.1-2(c) (1988).

rules further provide that: "Referral of contacts by HIV infected persons is strongly encouraged. Confidential contact tracing should be performed by trained public health disease control specialists. All identified contacts should receive counseling and be offered serologic testing."[104]

The Board's rules define a "contact" as "a person . . . that has been in an association with an infected person . . . which might provide an opportunity to acquire the infective agent."[105] The contact-tracing employed on those persons is the use of "epidemiologic methods to confidentially locate, counsel and refer for medical evaluation and possible treatment a contact of a person having a communicable disease.[106]

It is clear that the Board will know the identity of these reported patients. However, the rule does not explicitly require that each reported patient be contacted to identify any non-patient "contacts." The rule only provides "Referral of contacts by HIV infected persons is strongly encouraged."[107] The question then is whether the Board interprets that rule to *require* contact with each reported patient. The Board's internal policy statement[108] on "partner notification" describes a program aimed at infected persons at Counseling and Testing Sites (CTS) only.[109] Each person tested at such a site is requested by Board employees to identify potentially exposed partners in sex or needle-sharing. However, there is nothing in the policy applicable to the ordinary doctor who has an infected patient who is reported by name to the Board. It appears from the rules and the policy statements that there is *no program* for contacting those reported patients.

The statute does state that "All identified contacts should receive counseling and be offered serologic testing."[110] However, the "contacts" of the patients reported to the Board by a doctor will not receive this counseling unless the patient is first contacted and requested to identify the non-patient contacts. This does not seem to be part of the Board's contact-tracing program.

Thus, the Indiana program for reporting/contact-tracing does not appear to have all three components required to make it the substantial equivalent of the doctor's warning the non-patient. In Indiana, the

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104. *Id.* r. 1-2.1-7(b)(14).

105. *Id.* r. 1-2.1-1(e).

106. *Id.* r. 1-2.1-1(f).

107. *Id.* r. 1-2.1-1(e).

108. Indiana State Board of Health, Acquired Disease Division, Contact Notification Policy (Aug. 31, 1988).

109. A Counseling and Testing Site (CTS) is a place for anonymous testing of people for HIV infection. Persons tested at these sites cannot be reported using personal identifiers; rather they are to be reported using a numeric identifier code. IND. ADMIN. CODE tit. 410, r. 1-2.1-6(b)(14). Board employees do their contact-tracing by meeting the patient personally at the CTS. *Id.*

110. IND. CODE § 16-1-9.5-2.5(a) (1988).

doctor's duty of reasonable care to non-patients can apparently only be discharged by personally insuring that they are warned either by himself or in some cases by the patient.

V. Recent Indiana Non-Disclosure Statutes

A determination of whether the legislature has precluded the courts from creating a doctor's duty to warn requires an examination of Indiana legislation concerning HIV infection. Recent Indiana legislation provides that: "[A] person may not disclose or be compelled to disclose medical or epidemiological information involving a communicable disease or other disease that is a danger to health as defined under rules adopted under section 1 of this chapter."[111] The Board has adopted rules under that section which define HIV infection as a communicable disease and thus within this confidentiality provision.[112] The statute further provides: "Except as provided in subsection (a), a person responsible for . . . reporting . . . information required to be reported under this chapter who recklessly, knowingly or intentionally discloses or fails to protect medical or epidemiological information classified as confidential under this section commits a Class A misdemeanor."[113]

The statute forbidding disclosure of medical information about a person's HIV infection has several exceptions. The one pertinent here is that it allows "release" of the information "to protect the health or life of a named party."[114] This would allow a doctor to convey the medical information about his HIV infected patient to a non-patient only if the non-patient was "a named party." It is unclear what is meant by "a named party." There is no provision in the reporting statute or regulations for including the name of a third party in the report. They provide for reporting the *patient's* name but say nothing about any third party's name.

One possible interpretation of the phrase is that it allows a doctor to release medical information to protect the health or life of a non-patient that the doctor can reasonably identify and therefore "name." That would be a sensible limitation on the divulging of such information to third parties and is used in the violent patient statute. This interpretation could also explain why the 1988 version of the statute changed the language to "*a* named party,"[115] from the 1987 language of "*the*

111. Ind. Code § 16-1-9.5-7(a) (1988).
112. Ind. Admin. Code tit. 410, r. 1-2.1-2(d) (1988).
113. Ind. Code § 16-1-9.5-7(b) (1988).
114. *Id.* § 16-1-9.5-7(a)(3).
115. Act approved March 4, 1988, Pub. L. No. 123, § 4, 1988 Acts 1698, 1700.

named party."[116] The 1987 version most naturally referred to the *patient*, not a third party, because the patient is named in the doctor's report to the board. The 1988 version can be read as "a party named by the doctor as one known to the doctor to be at risk of HIV infection from the patient." If this interpretation of the statute is accepted then the non-disclosure statute contains an exception which *allows* the doctor to warn non-patients endangered by a patient. Therefore, the Indiana courts would not be foreclosed from recognizing an enforceable *duty* on the doctor to warn such a non-patient.

A second possible interpretation is that "a named party" refers only to the HIV infected *patient* named in the doctor's report to the Board. This implies the legislature intended no substantive change when it amended the 1987 version, "the named party" to "a named party" in 1988. Here the doctor would be permitted to divulge the information about his patient to another doctor, perhaps a specialist of some sort, in order "to protect the health or life" of the patient. That is a sensible rule and surely must be allowed in some form. However, if this second interpretation is accepted the statute forecloses the Indiana courts from recognizing the doctor's duty to warn such endangered non-patients by disclosing to them information about the HIV infected patient without that patient's consent.

This second interpretation would allow Board employees to do "contact tracing" in an attempt to prevent the non-patient's infection. They would do this by contacting the patient, named on the doctor's report, and request the patient to identify non-patients who may have or will be at risk of infection from the patient. Thus, notification of the non-patient is dependent upon the patient's willingness to identify such persons. If the patient does so, he or she has consented to the disclosure to the non-patient.[117] At this time the Board does not have a program for contacting the named patient to obtain the names of non-patients endangered by the patient, however, one could be instituted at any time.

In the absence of any controlling legislative history, the choice by a court between the two interpretations will turn on whether the court reasons that the legislature intended to preclude the courts from recognizing a doctor's duty to warn non-patients endangered by a patient's HIV infection. That the legislature intended such preclusion is rendered less plausible by the fact that the legislature imposed upon doctors a very similar duty to warn or take other reasonable precautions to protect

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116. Act approved April 24, 1987, Pub. L. No. 196, § 1, 1987 Ind. Acts 2272, 2275.

117. IND. CODE § 16-1-9.5-7(e) (1988), which provides that "[a]n individual may voluntarily disclose information about that individual's communicable disease."

third parties from serious harm from a violent patient.[118] Why would the legislature create that duty and then totally foreclose the creation of the same duty in the HIV infection case? Because the harm in both situations is serious, the only plausible way to explain such an inconsistency would be to impute the view to the legislature that the disclosure of the patient's HIV status is so much more harmful to the patient than disclosure of a patient's violent propensities, that disclosure of the former should not be allowed. If the legislature held that view, it could have made it clear in the non-disclosure statute. The existence of the inconsistency ought to be enough to cause a court to adopt the first interpretation which permits the judicial creation of a doctor's duty to warn. If the legislature does not agree, it always has the last word.

VI. Conclusion

In light of this analysis, several conclusions are discernible. First, the Indiana doctor is under an enforceable duty of confidentiality to the patient and there is ample precedent from other jurisdictions to allow an Indiana court to hold that a breach may be compensated in a civil damage suit. Second, there are no cases imposing on doctors a duty to warn non-patients exposed to HIV infection from a patient. However, Indiana has a statute creating such a duty in the case of violent patients and there are numerous cases from other jurisdictions imposing such a duty for other types of communicable diseases and for violent patients. Third, the Indiana program requiring the doctor to report HIV infected patients to the State Board of Health is not an adequate substitute for the doctor's personally warning the non-patient at risk from the patient. Therefore, the possibility is completely open for the Indiana courts to recognize a doctor's duty to warn a non-patient who has been or will be exposed to the HIV from the patient. Fourth, this possibility could be foreclosed by the legislature.

Thus, when the Indiana doctor determines that he or she has a HIV infected patient, the doctor is currently in a position of legal uncertainty concerning a duty to warn non-patients exposed to the virus by the patient. However, in the disease and violent patient cases and the Indiana statute on violent patients, the duty to warn has been found to outweigh the duty of confidentiality. There is no reason to believe that the Indiana courts will not reach this same conclusion when faced with the case of a HIV infected patient.

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118. *Id.* § 34-4-12.4-1 to -4.

Notes

The Work Made for Hire Doctrine Under the Copyright Act of 1976: Employees, Independent Contractors and the Actual Control Test

I. Introduction

A significant debate in copyright law involves the question of how to decide when a person creates a copyrightable work[1] within the scope of an employment relationship for purposes of determining copyright ownership. At the center of this debate is the application of the work made for hire doctrine which operates to vest in employers the copyrights to works prepared by their employees. The most contested issue under the doctrine involves works created by people who have characteristics of both independent contractors and employees.

The scope of the work made for hire doctrine covers a spectrum of potential employment relationships. At either end of the spectrum there is little dispute as to which party should own the copyright. At one end of the spectrum are the traditional employees.[2] Traditional employees are those who work for their employer in return for payment of a regular salary. The copyright to any artistic works created by these regular salaried

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1. Congress stated the general guidelines for determining what are copyrightable works as follows:

> (a) Copyright protection subsists, in accordance with this title, in original works of authorship fixed in any tangible medium of expression, now known or later developed, from which they can be perceived, reproduced, or otherwise communicated, either directly or with the aid of a machine or device. Works of authorship include the following categories:
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> (1) literary works;
> (2) musical works, including any accompanying words;
> (3) dramatic works, including any accompanying music;
> (4) pantomimes and choreographic works;
> (5) pictorial, graphic, and sculptural works;
> (6) motion pictures and other audiovisual works; and
> (7) sound recordings.
>
> (b) In no case does copyright protection for an original work of authorship extend to any idea, procedure, process, system, method of operation, concept, principle, or discovery, regardless of the form in which it is described, explained, illustrated, or embodied in such work.

17 U.S.C. § 102 (1982).

2. *See, e.g.*, Marshall v. Miles Laboratories, Inc., 647 F. Supp. 1326 (N.D. Ind. 1986).

employees always vests in the employer unless the parties agree otherwise.[3] At the opposite end of the spectrum are the independent contractors.[4] These individuals work alone with their own materials and they often create their works before communicating with prospective buyers. Generally, these artists own, or should own, the copyright to works they create.[5]

Between these two ends of the spectrum lie various fact situations in which the creators have characteristics of both employees and independent contractors. The uncertainty in the law arising in this muddled area of the spectrum, as illustrated by the recent split among the circuits of the United States Court of Appeals,[6] concerns the labeling of these artists as employees or independent contractors. The resulting characterization determines whether they will own the copyright to works they created. The disagreement among the circuits deciding work made for hire cases concerns the proper judicial test to use in determining the classification of these anomalous creators as employees or independent contractors.

Since the enactment of the Copyright Act of 1976,[7] the United States Supreme Court has had several opportunities to resolve this dispute among the courts of appeals but has yet to address the issue.[8] In the most recent case on the question, *Community for Creative Non-Violence v. Reid*,[9] the District of Columbia Circuit Court of Appeals rejected the holding in a

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3. However, critics of the present rule say that the copyright should vest in the employee/creator of the work regardless of whether it was created within the scope of his employment. *See, e.g.*, Comment, *Sufficiently Supervised Commissioned Workers: Mythical Beasts Sculpted from Old Law*, 14 PEPPERDINE L. REV. 381, 383-84 (1987) [hereinafter Comment, *Sufficiently Supervised Commissioned Workers*].

4. *See, e.g.*, Everts v. Arkham House Publishers, Inc., 579 F. Supp. 145 (W.D. Wis. 1984).

5. *Id.* at 149.

6. Community for Creative Non-Violence v. Reid, 846 F.2d 1485 (D.C. Cir.), *cert. granted*, 109 S. Ct. 362 (1988); Easter Seal Soc'y for Crippled Children & Adults of La., Inc. v. Playboy Enters., 815 F.2d 323 (5th Cir. 1987), *cert. denied*, 108 S. Ct. 1280 (1988); Brunswick Beacon, Inc. v. Schock-Hopchas Publishing Co., 810 F.2d 410 (4th Cir. 1987); Evans Newton Inc. v. Chicago Sys. Software, 793 F.2d 889 (7th Cir.), *cert. denied*, 479 U.S. 949 (1986); Aldon Accessories Ltd. v. Spiegel, Inc., 738 F.2d 548 (2d Cir.), *cert. denied*, 469 U.S. 982 (1984).

7. Pub. L. No. 94-553, 90 Stat. 2541 (codified at 17 U.S.C. §§ 101-810 (1982)).

8. *See* Easter Seal Soc'y for Crippled Children & Adults of La., Inc. v. Playboy Enters., 815 F.2d 323 (5th Cir. 1987), *cert. denied*, 108 S. Ct. 1280 (1988); Evans Newton Inc. v. Chicago Sys. Software, 793 F.2d 889 (7th Cir.), *cert. denied*, 479 U.S. 949 (1986); Aldon Accessories Ltd. v. Spiegel, Inc., 738 F.2d 548 (2d Cir.), *cert. denied*, 469 U.S. 982 (1984); Whelan Assocs. v. Jaslow Dental Laboratory, Inc., 609 F. Supp. 1307, *amended in part*, 609 F. Supp. 1325 (E.D. Pa. 1985), *aff'd*, 797 F.2d 1222 (3d Cir. 1986), *cert. denied*, 479 U.S. 1031 (1987).

9. 846 F.2d 1485 (D.C. Cir.), *cert. granted*, 109 S. Ct. 362 (1988).

similar case decided by the Second Circuit Court of Appeals in 1984[10] and adopted the view of the Fifth Circuit Court of Appeals.[11] The Supreme Court agreed to hear the case in the October 1988 term.[12]

Historically, the work made for hire doctrine favored employers. The United States Supreme Court first recognized the doctrine in the 1903 case of *Bleistein v. Donaldson Lithographing Co.*[13] Although the Court did not specifically set out the rule, the case nevertheless is cited by courts[14] and commentators[15] as the Supreme Court's first recognition of the doctrine that the copyrights to works created by employees within the scope of their employment belonged to their employers.[16]

In order to secure more rights for independent contractors,[17] Congress revised the work made for hire definition when it enacted the Copyright Act of 1976. The new definition provides as follows:

> A "work made for hire" is—
>
> (1) a work prepared by an employee within the scope of his or her employment; or
>
> (2) a work specially ordered or commissioned for use as a contribution to a collective work, as part of a motion picture or other audiovisual work, as a translation, as a supplementary work, as a compilation, as an instructional text, as a test, as answer material for a test, or as an atlas, if the parties expressly agree in a written instrument signed by them that the work shall be considered a work made for hire.[18]

Unfortunately, most independent contractors are no better off now than before the revision, primarily because Congress failed to define

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10. *Id.* at 1494 (rejecting Aldon Accessories Ltd. v. Spiegel, Inc., 738 F.2d 548 (2d Cir.), *cert. denied*, 469 U.S. 982 (1984)).

11. *Id.* (following Easter Seal Soc'y for Crippled Children & Adults of La., Inc. v. Playboy Enters., 815 F.2d 323 (5th Cir. 1987), *cert. denied*, 108 S. Ct. 1280 (1988)).

12. 109 S. Ct. 362 (1988).

13. 188 U.S. 239 (1903). *Bleistein* involved three lithographs created by the plaintiff's employees for the defendant's use in advertising its circus. The defendant later copied the designs in reduced form and the plaintiff sued for copyright infringement. *Id.* at 248.

14. *See, e.g.*, Murray v. Gelderman, 566 F.2d 1307, 1309 (5th Cir. 1978).

15. *See, e.g.*, Levin, *The Works Made For Hire Doctrine Under the Copyright Act of 1976—A Misinterpretation:* Aldon Accessories Ltd. v. Spiegel, Inc., 20 U.S.F. L. Rev. 649 (1987) [hereinafter Levin, *Misinterpretation*]; Simon, *Faculty Writings: Are They "Works Made For Hire" Under the 1976 Copyright Act?*, 9 J.C. & U.L. 485, 487 (1982-83).

16. 188 U.S. at 248 (citing Gill v. United States, 160 U.S. 426 (1896); Colliery Engineer Co. v. United Correspondence Schools Co., 94 F. 152 (C.C.S.D.N.Y. 1899); Carte v. Evans, 27 F. 861 (C.C.D. Mass. 1886)).

17. The 1976 Act provides that only certain categories of commissioned works fall within the scope of the works made for hire definition. 17 U.S.C. § 101 (1982).

18. *Id.*

"employer," "employee" or "scope of employment." Because many artists have characteristics of both employees and independent contractors, the courts have been compelled to devise their own tests to decide if a particular artist is an "employee" working "within the scope of his or her employment." The result has been the existing conflict among the circuit courts of appeals.[19]

On one side of the debate concerning works made for hire, writers, composers, painters, and other artists argue that they do not receive sufficient compensation for their creativity. Furthermore, they complain that, once a creation becomes a work made for hire, the artist loses all reproduction rights to the creation. To compensate for the meager living they earn selling their underpriced works, the artists want to retain reproduction rights to those works.[20]

In response to the artists' complaints, the publishers, motion picture producers, and other employers contend that, once they pay an artist to create a copyrightable work, the employer should own the reproduction rights to the work. They argue that employers incur serious financial risks in marketing the works.[21]

This Note will discuss the origins and history of the work made for hire doctrine in case law under the 1909 and 1976 Copyright Acts and will analyze attempts to devise a fair test for defining an employment relationship. This Note also will discuss the recent revision to the doctrine in the 1976 Copyright Act and problems interpreting the Act. Finally, this Note will show why the extent of actual control an employer exercises over the creation of a copyrightable work should be the determining factor in deciding whether an employment relationship exists.

II. Statutory Provisions Adopting the Work Made For Hire Doctrine and Court Interpretations

The framers of the Constitution recognized the importance of protecting those involved in the creative and useful arts.[22] They gave Congress

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19. Community for Creative Non-Violence v. Reid, 846 F.2d 1485 (D.C. Cir.), *cert. granted*, 109 S. Ct. 362 (1988); Easter Seal Soc'y for Crippled Children & Adults of La., Inc. v. Playboy Enters., 815 F.2d 323 (5th Cir. 1987), *cert. denied*, 108 S. Ct. 1280 (1988); Brunswick Beacon, Inc. v. Schock-Hopchas Publishing Co., 810 F.2d 410 (4th Cir. 1987); Evans Newton Inc. v. Chicago Systems Software, 793 F.2d 889 (7th Cir.), *cert. denied*, 479 U.S. 949 (1986); Aldon Accessories Ltd. v. Spiegel, Inc., 738 F.2d 548 (2d Cir.), *cert. denied*, 469 U.S. 982 (1984).

20. *See infra* notes 116-17 and accompanying text.

21. *See* Discussion and Comments on Report of the Register of Copyrights on the General Revision of the U.S. Copyright Law 109, 155 (1963), *reprinted in* G. Grossman, Part 2, 3 Omnibus Copyright Revision Legislative History (1976) (statement of Joseph Dubin) ("[The employer is] entitled to some consideration, too, for the financial investment he makes in the product that's finally a result of a composite endeavor of all people concerned.").

22. U.S. Const. art. I, § 8, cl. 8.

the power "To promote the Progress of Science and useful Arts by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[23] Congress employed this power to enact the Copyright Act of 1909.[24]

A. Copyright Act of 1909

The 1909 Copyright Act represented a codification of the work made for hire doctrine first recognized in *Bleistein v. Donaldson Lithographing Co.*[25] The 1909 Act stated that "the word 'author' shall include the employer in the case of works made for hire."[26] Obviously concerned with the constitutional provision empowering Congress to protect "authors" with respect to copyrights to their works, the drafters of the Act simply broadened the definition of "authors" so that it included the artists' employers. Interpretation problems with the 1909 Act arose because the works made for hire provision defined neither "employer" nor "works made for hire" and because the provision did not distinguish between regular employees and independent contractors.

1. Interpretations of the 1909 Act.—Because the 1909 Act did not define "employee," the earliest cases interpreting the 1909 Act were free to include independent contractors among "employees" in the works made for hire doctrine. In two early cases,[27] the United States Court of Appeals for the Second Circuit applied the doctrine to photographic portraits. The court held that when a person hires a photographer to take his picture and pays that photographer, the copyright belongs to the sitter, not the photographer, but a photographer who gratuitously solicits to photograph the sitter is owner of the copyright.[28] One commentator stated that the reason for vesting ownership of the copyright in the sitters in certain cases is that courts may have been concerned with the sitters' privacy rights not to have their likenesses reproduced without their consent.[29]

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23. *Id.*

24. Copyright Act of 1909, Pub. L. No. 349, ch. 320, 35 Stat. 1075 (1909) (repealed 1947).

25. 188 U.S. 239 (1903).

26. Copyright Act of 1909, Pub. L. No. 349, ch. 320, § 62, 35 Stat. 1075, 1088 (repealed 1947). *See* Pub. L. No. 281, ch. 391, § 26, 61 Stat. 652, 660 (1947) (repealed 1976). The 1909 Act also provided that "the works for which copyright may be secured under this Act shall include all the writings of an author." Copyright Act of 1909, Pub. L. No. 349, ch. 320, § 4, 35 Stat. 1075, 1076 (1909) (repealed 1947).

27. Lumiere v. Robertson-Cole Distributing Corp., 280 F. 550 (2d Cir.), *cert. denied*, 259 U.S. 553 (1922); Lumiere v. Pathe Exch., 275 F. 428 (2d Cir. 1921).

28. 280 F. at 552-53; 275 F. at 428.

29. STUDIES PREPARED FOR THE SUBCOMM. ON PATENTS, TRADEMARKS, AND COP-

Later, in *Yardley v. Houghton Mifflin Co.*,[30] the Second Circuit Court of Appeals applied its prior holdings to a painting. Again, the controlling factor was whether the artist received payment for his work.[31]

These holdings later developed into a more general "instance and expense" test enunciated in *Lin-Brook Builders Hardware v. Gertler*,[32] in which the Ninth Circuit Court of Appeals held:

> [W]hen one person engages another, whether as employee or as an independent contractor, to produce a work of an artistic nature, that in the absence of an express contractual reservation of the copyright in the artist, the presumption arises that the mutual intent of the parties is that the title to the copyright shall be in the person at whose *instance and expense* the work is done.[33]

In *Lin-Brook*, the plaintiff hired an artist to prepare drawings for its hardware catalogue. The defendants later displayed similar drawings in their hardware catalogue. Finding that the plaintiff, as the hiring party, owned the copyright in the drawings, the court held that the defendants infringed the plaintiff's copyright.[34]

A similar version of the instance and expense test appeared in *Picture Music, Inc. v. Bourne, Inc.*,[35] in which the Second Circuit Court of Appeals stated that the rationale for the works made for hire doctrine is that "the motivating factor in producing the work was the employer who induced the creation."[36] In *Murray v. Gelderman*,[37] the Fifth Circuit Court of Appeals, equating the instance and expense test with the

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YRIGHTS OF THE SENATE COMM. ON THE JUDICIARY, 86TH CONG., 2D SESS., STUDY NO. 13: WORKS MADE FOR HIRE AND ON COMMISSION 123, 142 n.58 (Comm. Print 1960) (authored by B. Varmer), *reprinted in* 1 G. GROSSMAN, OMNIBUS COPYRIGHT REVISION LEGISLATIVE HISTORY 123, 142 n.58 (1976) [hereinafter STUDY NO. 13].

30. 108 F.2d 28 (2d Cir. 1939), *cert. denied*, 309 U.S. 686 (1940).

31. *Id.* at 31.

32. 352 F.2d 298 (9th Cir. 1965).

33. *Id.* at 300 (emphasis added).

34. *Id.* at 300-02. *See also* Brattleboro Publishing Co. v. Winmill Publishing Corp., 369 F.2d 565 (2d Cir. 1966):

> [The works for hire doctrine] is applicable whenever an employee's work is produced at the *instance and expense* of his employer. In such circumstances, the employer has been presumed to have the copyright.
>
> We see no sound reason why these same principles are not applicable when the parties bear the relationship of employer and independent contractor.

Id. at 567-68 (citations omitted) (emphasis added).

35. 457 F.2d 1213 (2d Cir.), *cert. denied*, 409 U.S. 997 (1972).

36. *Id.* at 1216 (quoting Note, *Renewal of Copyright—Section 23 of the Copyright Act of 1909*, 44 COLUM. L. REV. 712, 716 (1944)).

37. 566 F.2d 1307 (5th Cir. 1978).

motivating factor test, held that a corporate employer owned the copyright to a book written by the hired party.[38] In addition, the court noted that the hired party cannot avoid the scope of the doctrine merely by demanding artistic freedom.[39]

Another factor courts developed to determine whether the work for hire doctrine applied to a creation under the 1909 Act, was the employer's right to supervise, direct, and exercise control over the manner in which the artist created his or her work. In *Scherr v. Universal Match Corp.*,[40] the Second Circuit Court of Appeals found this to be the most determinative factor in contrast to the "instance and expense" test which the court said was "pertinent but non-essential."[41] Actual exercise of the right to supervise was not controlling.[42]

A third factor used under the 1909 Act to determine if an employment relationship existed was the nature or existence of the compensation paid to the creator.[43] For example, in *Epoch Producing Corp. v. Killiam Shows, Inc.*,[44] the issue was whether D. W. Griffith directed and produced the film, *The Birth of a Nation*, as the employee for hire of the plaintiff, Epoch Producing Corp., or its predecessor, Majestic Motion Picture Co. The Second Circuit Court of Appeals held that no employment relationship existed between Griffith and either company.[45] In addition to finding a lack of supervision over Griffith, the court found no evidence that either company paid for the film's production. The court concluded that the film was not a work made for hire and, therefore, Epoch could not maintain a suit for copyright infringement against Killiam Shows.[46] Generally, however, the nature of compensation has been found to have lesser significance than the other factors.[47]

The extent of the overlap among these three factors was in dispute. In addition, courts took note of other factors, such as the bearing of

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38. *Id.* at 1310. *Compare* Siegel v. National Periodical Publications, Inc., 508 F.2d 909 (2d Cir. 1974) (work for hire did not exist with respect to comic strip because the comic strip was developed before employment relationship began and therefore was not produced at the instance and expense of the employer).

39. 566 F.2d at 1311.

40. 417 F.2d 497 (2d Cir. 1969), *cert. denied*, 397 U.S. 936 (1970).

41. *Id.* at 500. *See also* Picture Music Inc. v. Bourne, Inc., 457 F.2d 1213, 1216 (2d Cir.), *cert. denied*, 409 U.S. 997 (1972).

42. *Id.* at 501. *See also Murray*, 566 F.2d at 1310.

43. *Murray*, 566 F.2d at 1310; *see also Scherr*, 417 F.2d at 501. The courts did not expand on the meaning of the "nature" of compensation paid. Most likely, they were referring to a distinction between salaries or lump sum payments.

44. 522 F.2d 737 (2d Cir. 1975), *cert. denied*, 424 U.S. 955 (1976).

45. *Id.* at 744.

46. *Id.* at 745.

47. *See Murray*, 566 F.2d at 1310; *Scherr*, 417 F.2d at 501.

expenses and the place of creation, to determine if the works were created for hire.[48] The courts could agree only that they developed these factors tests to arrive at the intent of the parties to the relationship.[49]

Several of the factors tests used by these courts paralleled certain factors listed by the American Law Institute in its Restatement (Second) of Agency.[50] However, one court noted that these cases "developed into an almost irrebuttable presumption that any person who paid another to create a copyrightable work was the statutory 'author' under the 'work for hire' doctrine" which extended the class of "employee" well beyond the definition of "servant" under agency law.[51] Under this presumption, artists could not retain the copyrights in works they created unless they created the works entirely alone, in their own studies, and prior to contacting any interested buyers. Even under these circumstances, the artists would be wise to have the buyers agree in writing to let the artists retain the copyrights.

The original purpose of the factors tests was to arrive at the intent of the parties concerning copyright ownership when the parties did not

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48. *See* Dreyfuss, *The Creative Employee and the Copyright Act of 1976*, 54 U. CHI. L. REV. 590, 596 (1987).

49. *See, e.g.*, Lin-Brook Builders Hardware v. Gertler, 352 F.2d 298, 300 (9th Cir. 1965).

50. The Restatement provides as follows:

§ 220. Definition of Servant

(1) A servant is a person employed to perform services in the affairs of another and who with respect to the physical conduct in the performance of the services is subject to the other's control or right to control.

(2) In determining whether one acting for another is a servant or an independent contractor, the following matters of fact, among others, are considered:

(a) the extent of control which, by the agreement, the master may exercise over the details of the work;

(b) whether or not the one employed is engaged in a distinct occupation or business;

(c) the kind of occupation, with reference to whether, in the locality, the work is usually done under the direction of the employer or by a specialist without supervision;

(d) the skill required in the particular occupation;

(e) whether the employer or the workman supplies the instrumentalities, tools, and the place of work for the person doing the work;

(f) the length of time for which the person is employed;

(g) the method of payment, whether by the time or by the job;

(h) whether or not the work is a part of the regular business of the employer;

(i) whether or not the parties believe they are creating the relation of master and servant; and

(j) whether the principal is or is not in business.

RESTATEMENT (SECOND) OF AGENCY § 220 (1958).

51. Easter Seal Soc'y for Crippled Children & Adults of La., Inc. v. Playboy Enters., 815 F.2d 323 (5th Cir. 1987), *cert. denied*, 108 S. Ct. 1280 (1988).

express that intent. However, the courts used these tests to such an extent that they turned virtually every relationship into one of employer/employee. As a result, they defeated the original purpose of the factors tests. Artists who manage to retain their artistic freedom when they create works, in reality, do not intend to give all reproduction rights to employers who contributed nothing except funds to the creation.

B. Copyright Act of 1976

Because of the confusion existing under the 1909 Act's work made for hire provision, Congress found it necessary to reexamine and redefine the doctrine. The Copyright Act of 1976 provides for ownership of copyright as follows:

> (a) Initial Ownership.—Copyright in a work protected under this title vests initially in the author or authors of the work. The authors of a joint work are co-owners of copyright in the work.
>
> (b) Works Made for Hire.—In the case of a work made for hire, the employer or other person for whom the work was prepared is considered the author for purposes of this title, and, unless the parties have expressly agreed otherwise in a written instrument signed by them, owns all of the rights comprised in the copyright.[52]

Section 101 of the Act specifies which works should be considered "made for hire." The definition of works made for hire contains two parts. The first part includes "work[s] prepared by an employee within the scope of his or her employment."[53] The second part includes nine specific categories of commissioned works prepared by independent contractors whose employers may obtain the copyright if the parties sign a written agreement vesting copyright in the employer: (1) a contribution to a collective work; (2) a part of a motion picture or other audiovisual work; (3) a translation; (4) a supplementary work; (5) a compilation; (6) an instructional text; (7) a test; (8) answer material for a test; and (9) an atlas.[54] These categories clearly indicate Congressional intent to adopt prior law with respect to works prepared within the scope of the employment relationship.[55] However, Congress substantially revised the

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52. 17 U.S.C. § 201(a), (b) (1982).

53. 17 U.S.C. § 101 (1982).

54. *Id.*

55. H.R. REP. No. 1476, 94th Cong., 2d Sess. 121, *reprinted in* 1976 U.S. CODE CONG. & ADMIN. NEWS 5659, 5736. The report stated: "Section 201(b) of the bill adopts one of the basic principles of the present law: that in the case of works made for hire

rule for works prepared by independent contractors.[56]

There is little dispute over the status of works prepared in the typical employer/employee relationship (one in which the employee receives a regular salary from the employer and performs tasks pursuant to the employer's instructions). The employer owns the copyright unless a written agreement, signed by the parties, provides otherwise.[57] Furthermore, when it is clear that the creator of the work is an independent contractor (one who creates a work, completely alone, at the employer's request which merely describes a finished product), courts and commentators agree that the second part of the works made for hire definition governs the situation.[58] In other words, unless the work falls within one of the definition's nine categories and a written agreement gives the copyright to the employer, the copyright will vest in the independent contractor.[59]

The major subject of dispute concerns how to treat works created by those who have characteristics of both independent contractors and employees.[60] As the litigation in the work for hire area illustrates, scenarios frequently arise in which artists have characteristics of both independent contractors and employees in varying degrees.[61] Although

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the employer is considered the author of the work, and is regarded as the initial owner of copyright unless there has been an agreement otherwise." *Id.* This reflects an affirmation by Congress of the 1909 Act's statement that "the word 'author' shall include an employer in the case of works made for hire." Copyright Act of 1909, Pub. L. No. 349, ch. 320, § 62, 35 Stat. 1075, 1088 (repealed & reenacted 1947). *See* Pub. L. No. 281, ch. 391, § 26, 61 Stat. 652, 660 (1947) (repealed 1976).

56. H.R. Rep. No. 1476, 94th Cong., 2d Sess. 121, *reprinted in* 1976 U.S. Code Cong. & Admin News 5659, 5736-37.

57. 17 U.S.C. § 201(b) (1982).

58. *See, e.g.*, Easter Seal Soc'y for Crippled Children & Adults of La., Inc. v. Playboy Enters., 815 F.2d 323 (5th Cir. 1987), *cert. denied*, 108 S. Ct. 1280 (1988); Aldon Accessories Ltd. v. Spiegel, Inc., 738 F.2d 548, 552 (2d Cir.), *cert. denied*, 469 U.S. 982 (1984); Comment, *Sufficiently Supervised Commissioned Workers*, *supra* note 3.

59. 17 U.S.C. § 101 (1982).

60. *Compare Easter Seal*, 815 F.2d 323, *with Aldon*, 738 F.2d 548.

61. *See, e.g.*, Community for Creative Non-Violence v. Reid, 846 F.2d 1485 (D.C. Cir.), *cert. granted*, 109 S. Ct. 362 (1988) (employer exercised minimum control and guidance over commissioned artist); *Easter Seal*, 815 F.2d 323 (specially commissioned work during which plaintiff's representative gave layman's directions); Weinstein v. University of Illinois, 311 F.2d 1091 (7th Cir. 1987) (university professors are on a payroll but generally work independently); Evans Newton, Inc. v. Chicago Sys. Software, 793 F.2d 889 (7th Cir.), *cert. denied*, 479 U.S. 949 (1986) (plaintiff and defendant were in similar businesses and plaintiff gave some guidance to defendant); *Aldon*, 738 F.2d 548 (plaintiff worked closely with commissioned artists); Marshall v. Miles Laboratories, Inc., 647 F. Supp. 1326 (N.D. Ind. 1986) (salaried employee worked independently); Whelan Associates, Inc. v. Jaslow Dental Laboratory, Inc., 609 F. Supp. 1307, *amended in part*, 609 F. Supp. 1325 (E.D. Pa. 1985), *aff'd*, 797 F.2d 1222 (3d Cir. 1986), *cert. denied*,

the 1976 Act attempted to resolve this question, it did little to clear up the confusion.[62] The most obvious problem was that the Act did not include, within section 101, definitions for "employee" or "within the scope of one's employment." Furthermore, the legislative history reflected the assumption that the line between employees and independent contractors was a bright one and that it would be simple to determine whether a person fell into one category or the other.[63]

Because of the ambiguities in the new Act, the courts once again had to determine how to interpret the statute and what factors to consider in deciding whether to call someone an employee or an independent contractor.[64] The cases fall into three different categories of interpretation.[65]

1. The Literal Interpretation.—Some courts follow the literal interpretation of the Act, also called the radical interpretation because it adopts a radical change from prior law.[66] These courts hold that the two subsections of the Act's work made for hire definition are mutually exclusive.[67] In other words, under the literal interpretation, the first subsection includes only regular salaried employees. Subsection (2) of

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479 U.S. 1031 (1987) (plaintiff, computer programmer, consulted defendant concerning defendant's needs with regard to computer program, but then created program with little input from defendant); Mister B Textiles, Inc. v. Woodcrest Fabrics, Inc., 523 F. Supp. 21 (S.D.N.Y. 1981) (plaintiff's employee worked closely with commissioned fabric designer).

62. Because of the lack of a definition in the Act for "employee" some courts resorted to the pre-1976 factors tests used to distinguish employees from independent contractors under the 1909 Act. *See, e.g.*, Brunswick Beacon v. Schock-Hopchas Publishing Co., 810 F.2d 410 (4th Cir. 1987) (Hall, J., dissenting); Community for Creative Non-Violence v. Reid, 652 F. Supp. 1453 (D.D.C. 1987) *rev'd*, 846 F.2d 1485 (D.C. Cir.), *cert. granted*, 108 S. Ct. 362 (1988); Peregrine v. Lauren Corp., 601 F. Supp. 828 (D. Colo. 1985); Town of Clarkstown v. Reeder, 566 F. Supp. 137 (S.D.N.Y. 1983).

63. H.R. Rep. No. 1476, 94th Cong., 2d Sess. 121, *reprinted in* 1976 U.S. Code Cong. & Admin. News 5659, 5737.

64. *See Easter Seal*, 815 F.2d 323; *Aldon*, 738 F.2d 548; *Peregrine*, 601 F. Supp. 828.

65. The different methods of interpretation were set out in the most recent case on the subject, *Easter Seal*. *See also* O'Meara, *"Works Made for Hire" Under the Copyright Act of 1976—Two Interpretations*, 15 Creighton L. Rev. 523 (1981-82) [hereinafter O'Meara, *Two Interpretations*].

66. *See* O'Meara, *Two Interpretations*, *supra* note 65.

67. *See, e.g.*, May v. Morganelli-Heumann Assocs., 618 F.2d 1363 (9th Cir. 1980); Whelan Assocs. v. Jaslow Dental Lab, Inc., 609 F. Supp. 1307 (E.D. Pa. 1985), *amended in part*, 609 F. Supp. 1325 (E.D. Pa. 1985) *aff'd*, 797 F.2d 1222 (3d Cir. 1986), *cert. denied*, 479 U.S. 1031 (1987); Everts v. Arkham House Publishers, Inc., 579 F. Supp. 145 (W.D. Wis. 1984); Childers v. High Soc'y Magazine, Inc., 557 F. Supp. 978, *aff'd on rehearing*, 561 F. Supp. 1374 (S.D.N.Y. 1983); Mister B Textiles, Inc. v. Woodcrest Fabrics, Inc., 523 F. Supp. 21 (S.D.N.Y. 1981); Meltzer v. Zoller, 520 F. Supp. 847 (D.N.J. 1981).

the definition enumerates the only categories of independent contractors (assumed to be anyone who is not a regular salaried employee) which may be subject to the work for hire doctrine. Employers commissioning works covered by subsection (2) must meet the additional requirement that both parties sign an agreement that the creations should be considered works made for hire.

A recent case applying the literal interpretation of the 1976 Act is *Easter Seal Society For Crippled Children and Adults of Louisiana, Inc. v. Playboy Enterprises*.[68] The Fifth Circuit Court of Appeals noted in *Easter Seal* the three different interpretations of the 1976 Act: the literal interpretation, discussed above, the conservative interpretation which holds that the 1976 Act did little to change prior law, and the *Aldon Accessories*[69] compromise. In *Aldon*, the Second Circuit held that an employer hiring an artist to create a specific work must at least exercise actual control over the manner in which the artist created his work for that artist to be considered an employee of the commissioning party.[70] The *Easter Seal* court rejected the *Aldon* compromise, stating that it misinterpreted the statute, and adopted the literal interpretation.[71]

The *Easter Seal* case involved the creation of videotapes of a staged "Mardi Gras" style parade and a "Dixieland" musical jam session for the plaintiff, Easter Seal, and the alleged unauthorized use of parts of the videotape by the defendant, Playboy, in an adult film.[72] The original videotapes were created and edited for use in a National Easter Seal Telethon. The principal parties who created the videotape were entertainer Ronnie Kole, working on behalf of Easter Seal, and the employees of New Orleans public television station WYES. Although Kole was the principal "on camera" actor, he gave only layman's suggestions regarding the technical aspects of filming the "parade" and jam session. The WYES staff made the final aesthetic and technical decisions and created the finished edited version from the "raw video footage."[73]

The court thoroughly discussed the cases under the 1909 Act and the three interpretations under the 1976 Act and then addressed several defects in the literal interpretation.[74] First, the court noted that the language in section 201(b), providing that "[i]n the case of a work made for hire, the employer *or other person for whom the work was prepared*

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68. 815 F.2d 323 (5th Cir. 1987), *cert. denied*, 108 S. Ct. 1280 (1988).

69. Aldon Accessories Ltd. v. Spiegel, Inc., 738 F.2d 548 (2d Cir. 1984). For a discussion of *Aldon*, see *infra* notes 95-107 and accompanying text.

70. 738 F.2d at 552.

71. *Easter Seal*, 815 F.2d at 334.

72. *Id.*

73. *Id.* at 324.

74. *Id.* at 325-34.

is considered the author for purposes of this title," is too broad to be consistent with requirements of the subsection 101(2).[75] The court found this language to be more like "an affirmation of the 1909 Act 'work for hire' doctrine."[76] The court then stated that if Congress intended a literal reading of the statute, which would result in a radical departure from prior law, there would have been more discussion in the legislative history to indicate that intention.[77]

Despite its concerns regarding the literal interpretation, the court adopted that view.[78] Recognizing that this ruling was a "radical break from the 'work for hire' doctrine under the 1909 Act,"[79] the court noted that "a work is 'made for hire' within the meaning of the Copyright Act of 1976 if and only if the seller is an employee within the meaning of agency law, or the buyer and seller comply with the requirements of § 101(2)."[80]

The court concluded that the literal view was the most sensible interpretation of the actual language used in the 1976 definition of work made for hire given the vague language and structure of the Act's definition.[81] In support of its conclusion, the court emphasized the division in the definition between employees' works in the first part and the nine specific kinds of specially commissioned works in the second part.[82] Although the court did not expressly mention the importance of a regular salary as the distinguishing characteristic of an employee, its discussion implies that only those artists receiving a regular salary may be called employees.

In a more recent case, *Community for Creative Non-Violence v. Reid*,[83] the District of Columbia Circuit reversed the district court which

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75. *Id.* at 330 (emphasis in original).

76. *Id.* Actually the words "or other person for whom the work was prepared" can be read consistently with any one of the three interpretations. *See infra* text accompanying notes 141-43.

77. *Id.* at 330-31. The court noted that, under the 1909 Act, buyers of commissioned works were almost always the "authors." The court said that, if the 1976 Act is read literally, it represents a fundamental change in the work for hire doctrine as it applies to independent contractors. Independent contractors, under a literal interpretation of the new Act, are almost always the statutory "authors." *Id.*

78. *Id.* at 334.

79. *Id.* at 335.

80. *Id.* at 334-35. The requirements of the second part of the work for hire definition are that the work be one of the nine types of works enumerated in that section and that the parties agree in writing that the work is a work made for hire. Although the court approved of the Restatement definition of employee which adopts the right to control test, *see supra* note 50, the court contradicted itself and rejected other cases adopting the right to control test.

81. *Id.* at 335.

82. *Id.*

83. 846 F.2d 1485 (D.C. Cir.), *cert. granted*, 109 S. Ct. 362 (1988).

relied on the pre-1976 factors tests to determine whether a sculptor was an employee or independent contractor.[84] In this case, the Community for Creative Non-Violence ("CCNV") hired a sculptor to create a statute for CCNV's display in the Christmas Pageant of Peace on the Ellipse in Washington, D.C. The agent for CCNV developed the basic idea for the statute, a modern Nativity scene with a homeless family, in place of the traditional Holy Family, huddled over a streetside steam grate.[85]

CCNV's agent provided the sculptor with human models to pose for the work and took him to view steam grates, and some other CCNV members visited him on occasion to check his progress. No one from CCNV directed the sculptor during the process of creating the statue.[86] The district court held, however, that the statue was a work made for hire because CCNV was the motivating factor in the statue's creation and because CCNV had the right to direct the manner in which the statue was created.[87]

In reversing the district court, the court of appeals followed *Easter Seal*'s literal interpretation of the Act.[88] The court further solidified the literal view by discarding the doubts expressed by the *Easter Seal* court.[89]

2. The Conservative Interpretation.—In contrast to the literal view, fewer courts have relied on the conservative interpretation of the 1976 Act.[90] The conservative interpretation applies the factors tests developed in cases decided under the 1909 Act to determine whether an artist is an "employee" under the first part of the section 101 definition of work made for hire.[91] Therefore, if the work was created at the instance and expense of the buyer or if the buyer had the right to supervise the manner in which the work was created, then the creator became an "employee" under the first part of section 101.[92] The specific categories

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84. Community for Creative Non-Violence v. Reid, 652 F. Supp. 1453, 1456 (D.D.C. 1987), *rev'd*, 846 F.2d 1485 (D.C. Cir.), *cert. granted*, 109 S. Ct. 362 (1988). *See supra* notes 32-49 and accompanying text for descriptions of these factors tests.

85. 846 F.2d at 1487 (quoting 652 F. Supp. at 1454).

86. 652 F. Supp. at 1455.

87. *Id.* at 1456.

88. *Id.* at 1494.

89. *Id.*

90. *See, e.g.*, Brunswick Beacon, Inc. v. Schock-Hopchas Publishing Co., 810 F.2d 410 (4th Cir. 1987) (Hall, J., dissenting); Community for Creative Non-Violence v. Reid, 652 F. Supp. 1453 (D.D.C. 1987) *rev'd*, 846 F.2d 1485 (D.C. Cir.), *cert. granted*, 109 S. Ct. 362 (1988); Peregrine v. Lauren Corp., 601 F. Supp. 828 (D. Colo. 1985); Town of Clarkstown v. Reeder, 566 F. Supp. 137 (S.D.N.Y. 1983).

91. *See, e.g.*, *Peregrine*, 601 F. Supp. at 829 (citing Lin-Brook Builders Hardware v. Gertler, 352 F.2d 298 (9th Cir. 1965)); *Town of Clarkstown*, 566 F. Supp. at 141 (citing Epoch Producing Corp. v. Killiam Shows, Inc., 522 F.2d 737, 744 (2d Cir. 1975), *cert. denied*, 424 U.S. 955 (1976)).

92. 17 U.S.C. § 101 (1982).

under the second part of section 101 are the only commissioned works which are not works made for hire unless the parties signed an agreement stating that the works are made for hire.[93]

> In other words, paragraph (1) of the definition restates the existing case law where, for copyright purposes, an independent contractor is considered to be an employee. Paragraph (2) carves out exceptions to the old case law comprising specially commissioned works not considered works made for hire in the absence of a writing executed by both parties.[94]

While the literal interpretation results in a substantial change in prior law, courts following the conservative view assume that Congress intended very little change in prior law.

3. The Aldon Compromise.—In a 1984 case, *Aldon Accessories Ltd. v. Spiegel, Inc.*,[95] the Second Circuit Court of Appeals devised a compromise between the two conflicting views underlying the literal and conservative interpretations. In *Aldon*, the court held that if the employer hiring someone to create a copyrightable work exercises sufficient supervision and control over the manner in which the artist creates the work, then the employer is the author of the work under the first part of section 101.[96]

This actual control requirement differs from the literal interpretation in that it encompasses more situations than those involving regular salaried employees. In contrast to the conservative interpretation under which *right* to control is sufficient to find an employer/employee relationship, this view requires at least *actual* supervision by the employing party.[97]

The plaintiff in this case, Aldon, was a company formed by two brothers. Aldon designed and marketed figurines and other pieces for interior design. In 1977, one of the brothers, Arthur Ginsberg, contacted a Japanese trading firm about creating statuettes representing mythological creatures, including a unicorn and a Pegasus. Ginsberg also sent sketches of his idea and worked closely with the artists hired by the trading company in developing models of the horse-like figures.[98] In

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93. *Id.*
94. O'Meara, *Two Interpretations*, *supra* note 65, at 528.
95. 738 F.2d 548 (2d Cir. 1984), *cert. denied*, 469 U.S. 982 (1984).
96. *Id.* at 552-53.
97. *Id.* at 552.
98. *Id.* at 549. The court related that "Ginsberg testified at length as to the precise nature of his interaction with the artists. The gist of his testimony was that while he is not an artist and did not do the sketching or sculpting, he actively supervised and directed the work step by step." *Id.* at 550.

1981, Aldon displayed samples of the finished statuettes at a trade show. A buyer for Spiegel attended the show and expressed an interest in the statuettes. Although Spiegel did not purchase any of the statuettes from Aldon, Ginsberg later noticed that Spiegel advertised the same pieces in the Spiegel catalogues. Spiegel's actions prompted Aldon to file suit for copyright infringement. Aldon contended that the statuettes were works made for hire and, therefore, Aldon was the owner of the copyright.[99]

Spiegel argued, following the literal interpretation of the Act, that the Japanese trading company and its hired artists constituted independent contractors because they were not regular salaried employees of Aldon. Therefore, only subdivision (2) of the works made for hire definition would apply. Spiegel contended that, because sculpture is not included among the nine narrow categories in subdivision (2), the statuettes could not be works for hire and, therefore, Spiegel did not infringe Aldon's alleged copyright.[100]

The Second Circuit agreed with Spiegel that, if the case were to be governed by subdivision (2) of the definition, the statuettes would not be works made for hire.[101] However, the court found that Spiegel gave an overly restrictive interpretation of the first part of the definition.[102] The court concluded that the statuettes were, in fact, works prepared by an employee within the scope of his employment.[103] The court discussed the 1976 Act's effect on prior law:

> Under the 1909 Act and decisions construing it, if an employer supervised and directed the work, an employer-employee relationship could be found even though the employee was not a regular or formal employee. Nothing in the 1976 Act or its legislative history indicates that Congress intended to dispense with this prior law applying the concepts of "employee" and "scope of employment." The new Act does not define these key terms, thus suggesting that it is necessary to look at the general law of agency as applied by prior copyright cases in applying subdivision (1) under the new Act.[104]

The court thus found that the 1976 Act changed only the treatment of independent contractors.[105]

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99. *Id.* at 549-50.
100. *Id.* at 551.
101. *Id.*
102. *Id.*
103. *Id.* at 551-52.
104. *Id.* at 552 (citations omitted).
105. *Id.*

The court noted that cases decided under the 1909 Act showed that a presumption existed, even in the case of independent contractors, that the hiring party owned the copyright unless contrary proof existed.[106] The 1976 Act, according to *Aldon*, switched the burden by creating the presumption that, in the absence of contrary proof, the work prepared by an independent contractor on special order or commission was not a work for hire.

The court then noted that cases cited by Spiegel in favor of the literal interpretation were compatible with the court's decision because the same question still remains: what is an employee working within the scope of his employment?[107] Therefore, the only difference between *Aldon* and the cases favoring the literal interpretation is that the *Aldon* court looked into the relationship between the hiring party and the creator and applied agency principles to determine if an employment relationship existed. The literalists, on the other hand, summarily assumed that an employment relationship did not exist unless the creator was a regular salaried employee.

In summary, the differences among the three interpretations of the 1976 Act's definition of works made for hire center on Congress' failure to define "employee" or "scope of employment." The literal view implicitly assumes that only those artists receiving a regular salary are employees. The conservative view uses the factors tests that arose under 1909 Act cases to determine if an artist is an employee. Finally, the *Aldon* actual control test requires a finding that an employer exercised sufficient supervision and control over an artist for an employment relationship to exist.

Another method of comparing the three interpretations is to visualize a spectrum of factual situations in which one end comprises undisputed independent contractors and the other end comprises undisputed employees.[108] The middle of the spectrum includes artists having characteristics of both employees and independent contractors.

Under the literal interpretation, almost all artists on the spectrum are independent contractors because anyone not receiving a regular salary is an independent contractor. Under the conservative interpretation, almost all the artists are employees because the effect of the factors tests (the right to control test, the instance and expense test and the nature of compensation test) is to include almost all artists in the category of

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106. *Id.*

107. *Id.* The court held: "but that simply frames the issue: is the contractor 'independent' or is the contractor so controlled and supervised in the creation of the particular work by the employing party that an employer-employee relationship exists." *Id.*

108. *See supra* notes 2-6 and accompanying text.

"employee." The division between employee and independent contractor under the *Aldon* actual control test is closer to the middle of the spectrum. Not everyone who hires an artist to create a particular work will exercise control over the creation of the work to the extent that the employer's input is reflected in the final product. For those employers who exercise sufficient control, the artists will be considered their "employees" under the work made for hire doctrine.

III. Analysis: Reviving *Aldon*

Since the Second Circuit handed down its decision in *Aldon*, courts and commentators in favor of the literal interpretation have rallied against the actual control test.[109] Although some of the criticism stands on solid ground, many of *Aldon*'s critics fail to recognize the advantages that the *Aldon* compromise has over both the literal and conservative views. The remainder of this Note will discuss the strengths and weaknesses of the three interpretations and why the decision in *Aldon* is the most favorable for curing the ambiguities left by the new Act's failure to define "employee." This Note stands alone in its support for the *Aldon* actual control test. Nonetheless, an overview of the three interpretations will reveal that the actual control test is more consistent with the legislative history of the Act and with agency law principles and that the actual control test is workable and equitable.

A. The Conservative Interpretation is Inconsistent With Legislative History and Causes Courts to Reach Inequitable Decisions

As stated above, the conservative interpretation of the 1976 Act's definition of works made for hire assumes little change from prior law.[110] The support for this view comes from Congress' adoption of the prior work made for hire doctrine as it applies to employees. The legislative history states: "Section 201(b) of the bill adopts one of the basic principles of the present law: that in the case of works made for hire the employer is considered the author of the work, and is regarded as the initial owner of copyright unless there has been an agreement otherwise."[111]

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109. *See, e.g.*, Community for Creative Non-Violence v. Reid, 846 F.2d 1985 (D.C. Cir.), *cert. granted*, 109 S. Ct. 362 (1988); Easter Seal Soc'y for Crippled Children and Adults of La., Inc. v. Playboy Enterprises, 815 F.2d 323 (5th Cir. 1987), *cert. denied*, 108 S. Ct. 1280 (1988); Comment, *The Works Made for Hire Doctrine of the 1976 Copyright Act After* Aldon Accessories Ltd. v. Spiegel, Inc., 5 Cardozo Arts and Ent. L. Rev. 265 (1986); Levin, *Misinterpretation*, *supra* note 15; Comment, *Sufficiently Supervised Commissioned Workers*, *supra* note 3.

110. *See supra* text accompanying notes 91-94.

111. H.R. Rep. No. 1476, 94th Cong., 2d Sess. 121, *reprinted in* 1976 U.S. Code Cong. & Admin. News 5659, 5736.

This statement, together with the absence of a definition for "employee" or "scope of employment" and the provision giving copyright of a work made for hire to "the employer *or other person for whom the work was prepared*,"[112] led conservative courts to apply the pre-1976 tests to possible work for hire situations. Consequently, these courts distinguished independent contractors from employees by the employer's "right to control" the employee, by determining "at whose instance and expense" the work was created, and by the "nature of compensation" paid to the employee.[113]

One obvious defect with the conservative view is its inconsistency with a later provision in the legislative history dealing with independent contractors which states as follows:

> The status of works prepared on special order or commission was a major issue in the development of the definition of "works made for hire" in section 101, which has undergone extensive revision during the legislative process. The basic problem is how to draw a special order or commission that should be considered "works made for hire," and those that should not. The definition now provided by the bill represents a compromise which, in effect, spells out those specific categories of commissioned works that can be considered "works made for hire" under certain circumstances.[114]

This statutory line-drawing by Congress gives the impression that, considering the lack of a detailed definition for "employee," the distinction between employees and independent contractors is obvious and is consistent with the view that only regular salaried artists are employees. The specially-commissioned works section would cover all other artists even if they also have characteristics of employees. The result of this assumption would be that no artist/independent contractor would cross the statutory line toward becoming an "employee" regardless of how much control an employer exercised over the manner in which the artist created the work.

A second defect in the conservative view is that, if Congress intended prior law to govern under the new Act, it would not have revised the

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112. 17 U.S.C. § 201(b) (1982) (emphasis added).

113. *See, e.g.*, Community for Creative Non-Violence v. Reid, 652 F. Supp. 1453 (D.D.C. 1987) *rev'd*, 846 F.2d 1485 (D.C. Cir.), *cert. granted*, 109 S. Ct. 362 (1988); Brunswick Beacon, Inc. v. Schock-Hopchas Publishing Co., 810 F.2d 410, 414-15 (4th Cir. 1987) (Hall, J., dissenting); Peregrine v. Lauren Corp., 601 F. Supp. 828 (D. Colo. 1985); Town of Clarkstown v. Reeder, 566 F. Supp. 137 (S.D.N.Y. 1983).

114. H.R. Rep. No. 1476, 94th Cong., 2d Sess. 121, *reprinted in* 1976 U.S. Code Cong. & Admin. News 5659, 5737.

1909 Act's statement of the doctrine.[115] Clearly, Congress intended to enact some change in the determination of works for hire. The conservative interpretation contradicts this obvious conclusion.

The most important problem with the conservative interpretation is that it causes courts to reach inequitable decisions. Freelance artists suffered inequities because they received little compensation for their creations[116] and because, under the 1909 Act and cases construing it (and cases following the conservative interpretation under the 1976 Act), they lost all reproduction rights to their work. One of Congress' purposes in changing the doctrine was to avoid these inequities that independent artists had suffered for too long.[117]

One example of the inequitable results of the conservative interpretation is *Peregrine v. Lauren Corp.*[118] In *Peregrine*, a federal district court found that an advertising agency that hired a photographer to take photographs for a brochure was the owner of the copyright to the photos under the work made for hire doctrine.[119] The court reached this decision despite its specific finding that the photographer was an independent contractor.[120] The court found that the photographs were

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115. *Compare* Copyright Act of 1909, Pub. L. No. 349, ch. 320, 35 Stat. 1075 (1909) (repealed 1947) *with* 17 U.S.C. § 101 (1982).

116. One freelance illustrator, Robin Brickman, testified before the Committee on the Judiciary concerning her earnings as a freelance artist under the 1976 Act. Her 1979 income was $6,995. In 1980, her income was $8,455, fifty-nine percent of which came from work made for hire. *A Bill to Amend the Copyright Law Regarding Work for Hire: Hearing on S. 2044 Before the Senate Committee on the Judiciary*, 97th Cong., 2d Sess. 3 (1982) (statement of Robin Brickman).

117. For example, during the debates before Congress, one of the commentators recited the following examples:

> I give the example of a lady who came in to me with a paper, and said, "I have written half a dozen songs. I took them to a recording company and they've given me this contract to sign. Shall I sign it?" . . . I looked at the contract, which provided: "We hereby employ you to write the following songs." The songs had been written 6 months before, but she didn't know that the proposed contract, drawn ostensibly as an employment agreement, would have given to the recording company the renewal rights in the copyright.

Hearings Before the Subcommittee on Patents, Trademarks, and Copyrights of the Committee of the Judiciary 55, 106-07 (1961), *reprinted in* 3 G. GROSSMAN, OMNIBUS COPYRIGHT REVISION LEGISLATIVE HISTORY 55, 106-07 (1976) (statement of John Schulman).

118. 601 F. Supp. 828 (D. Colo. 1985).

119. *Id.* at 829.

120. *Id.* The court stated:

> Given that defendant's method of paying Mr. Peregrine points toward a finding that Mr. Peregrine was an independent contractor rather than an employee, it is instructive to consider the longstanding presumption that the mutual intent of the parties to the creation of an artistic work, whether employer/employee or independent contractor, was to vest title to the copyright in the person at whose insistence and expense the work was done.

Id. (citing Lin-Brook Builders Hardware v. Gertler, 362 F.2d 298 (9th Cir. 1965)).

taken at the insistence of the advertising agency and that the agency also had the right to supervise the work.[121]

This dispute arose from the advertising agency's refusal to pay for the photographs because the agency thought the charge was excessive. The court, finding for the agency, stated that the photographer was free to proceed in a state court for *quantum meruit* collection.[122] As a result, not only did the photographer lose the copyright to the photographs[123] and the right to withhold delivery of them (the dispute over price arose after the plaintiff delivered the photographs), but he also lost the right to bargain for his loss of copyright in the price for the photographs.

This case shows how the conservative interpretation leads to results which defeat the purpose for changing the doctrine in the first place.[124] The purpose for revising the Act was to provide more opportunities for freelance artists to retain the copyright in their works. However, the cases following the conservative view put these artists in the same position as before 1976. Few courts have used the conservative interpretation and that view, because of its unfairness to freelance artists, probably will fall into disuse.

B. The Literal Interpretation is Inflexible and Inconsistent With Agency Law Principles

The literal interpretation assumes that Congress intended a radical change from prior law in the work made for hire doctrine. This view has several points in its favor. The first point cited by courts which have adopted this view concerns the structure of the statute itself.[125] The definition of works made for hire under section 101 is divided into two

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121. *Id.* The court found:

> Although Mr. Peregrine made suggestions during the course of the shooting sessions which were followed more often than not, it is clear that at any point the employer could have vetoed any of Mr. Peregrine's ideas or otherwise radically changed the course, scope or fact of Mr. Peregrine's photographic exertions on the project.

Id.

122. *Id.* at 830.

123. *Id.* at 829.

124. *See also* Joseph J. Legat Architects v. United States Dev. Corp., 625 F. Supp. 293 (N.D. Ill. 1985) (finding that the decisive factor, whether the alleged employer had the right to direct and supervise the manner in which the work was performed, did not make architectural plans works made for hire only because of the custom in the profession that an architect uses independent judgment in drawing plans); Town of Clarkstown v. Reeder, 566 F. Supp. 137 (S.D.N.Y. 1983).

125. *See, e.g.*, Easter Seal Soc'y for Crippled Children & Adults of La., Inc. v. Playboy Enters., 815 F.2d 323 (5th Cir. 1987), *cert. denied*, 108 S. Ct. 1280 (1988); Levin, *Misinterpretation*, *supra* note 15.

subsections.[126] The plain language of the statute, along with its legislative history referring to the change in treatment of independent contractors,[127] gives one the impression that Congress intended the first half of the definition to include only regular employees on a payroll and the second half to include everyone else.

Although all three interpretations refer to the factors listed in section 220 of the Restatement (Second) of Agency,[128] the literal view applies a much stricter standard in determining what factors, if present, are sufficient to conclude that an employment relationship exists. For example, although the Restatement places significant emphasis on the employer's control or right to control the manner in which the worker performs his work,[129] the literal interpretation requires more evidence of an employment relationship. The literalists would require the employer to have the worker on the payroll and to provide the worker with benefits available to salaried employees, and would require the employer to withhold social security and income taxes before characterizing the relationship as that of employer and employee.[130] In a scenario involving what initially appears to be that of employer and independent contractor, where the employer exercises control over the work being performed, application of the literal interpretation would result in a conclusion that a joint work,[131] rather than a work for hire, was created.[132]

The literal view is preferable to the conservative view because it excludes more freelance artists from the work made for hire characterization, thereby giving more credit to the actual creator of the work.

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126. 17 U.S.C. § 101 (1982).

127. H.R. Rep. No. 1476, 94th Cong., 2d Sess. 121, *reprinted in* 1976 U.S. Code Cong. & Admin. News 5659, 5737.

128. Restatement (Second) of Agency § 220 (1958), *supra* note 50, *quoted in Easter Seal*, 815 F.2d at 335 n.20.

129. The Restatement (Second) of Agency, section 220 comment e distinguishes between employees and independent contractors as follows:

> The important distinction is between service in which the actor's physical activities and his time are surrendered to the control of the master, and service under an agreement to accomplish results or to use care and skill in accomplishing results. Those rendering service but retaining control over the manner of doing it are not servants.

Restatement (Second) of Agency § 220 comment e (1958).

130. Comment, *Sufficiently Supervised Commissioned Workers*, *supra* note 3, at 387-88.

131. "A 'joint work' is a work prepared by two or more authors with the intention that their contributions be merged into inseparable or interdependent parts of a unitary whole." 17 U.S.C. § 101 (1982). The 1976 Act provides that "[t]he authors of a joint work are coowners of copyright in the work." 17 U.S.C. § 201(a) (1982).

132. *See, e.g.*, Mister B Textiles, Inc. v. Woodcrest Fabrics, Inc., 523 F. Supp. 21 (S.D.N.Y. 1981).

Some freelancers will not be able to avoid having their work characterized as a work made for hire if a contract is signed to that effect. Other freelancers, however, will own the copyright to works they created because their works will not fall into one of the nine categories in part two of the definition, notwithstanding the existence of a contract calling the creation a work made for hire.

For instance, had the federal district court in *Peregrine v. Lauren Corp.*[133] followed the literal interpretation of the Act, it undoubtedly would have found the plaintiff was an independent contractor. The photographer's copyright could not be signed away through the use of a contract calling his photographs works made for hire. Because photographs are not among the works enumerated in section 101's definition regarding specially commissioned works, an employer's use of a contract calling photographs works made for hire would be insufficient to vest the copyright in the employer.

In a factually similar case, *Childers v. High Society Magazine, Inc.*,[134] another federal district court did, in fact, find for a freelance photographer by following the literal interpretation. In *Childers*, the plaintiff, a professional photographer, photographed well-known actresses whose portraits were then marketed by Sygma Photo News, Inc., agent for the sale of one-time, non-exclusive reproduction rights to the photographs.[135] When certain of these photographs appeared on covers of High Society Magazine, the photographer sued the magazine and its publisher for unauthorized use.[136]

In granting plaintiff's motion for summary judgment, the court stated the obvious—that the plaintiff was never the "employee" of the actresses for purposes of the first half of section 101 of the Act.[137] The court then found that the photographs did not fall under the second half of section 101 because the parties executed no written contract to vest copyright in the actresses and because photographs are not listed among the nine categories in that subsection.[138]

Despite its advantages over the conservative view, the literal view also contains defects. Most important among these defects is the literalists' assumption that the statutory definition of employee includes only those workers who are on the regular payroll of their employers. The word "employee" was not defined in the new Act. Therefore, "employee"

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133. 601 F. Supp. 828 (D. Colo. 1985). See *supra* text accompanying notes 118-23 for a discussion of this case.

134. 557 F. Supp. 978, *aff'd on rehearing*, 561 F. Supp. 1374 (S.D.N.Y. 1983).

135. 557 F. Supp. at 980.

136. *Id.* at 982.

137. *Id.* at 984.

138. *Id.*

must be interpreted to have its common law meaning[139] which, contrary to the literal interpretation, includes more than regular salaried employees.

In addition, the lack of discussion in the legislative history of the Act contradicts the literalists' view that Congress intended to radically change prior law. Congress expressly adopted the common law presumption that employers own the copyright to any works created by their employees within the scope of their employment.[140] This is an affirmation of prior law, not a radical departure from prior law. Furthermore, the provision that the employer "or other person,"[141] for whom a work is created owns the copyright indicates Congress' reluctance to radically change the doctrine.

Of course, the phrase "or other person" could be interpreted as consistent with either the literal or conservative view. Under the literal view, "or other person" can be said to mean those limited employers in the nine narrow categories of the second part of the work made for hire definition.[142] Under the conservative view, "or other person" would be anyone found to be an employer under the pre-1976 tests.[143]

However, the phrase "or other person" indicates an intention to arrive at a compromise between prior law under which virtually all artists were "employees" and a definition that would call all artists independent contractors. If Congress did intend "or other person" to mean only those qualifying under the second part of the definition, it could easily have stated such an intention. For example, Congress could have written section 201 to vest copyright in the "employer of a creator who is on the employer's regular payroll, or commissioning party who qualifies under section 101(2) of the work made for hire definition."

Another troubling aspect of the literal interpretation is that this view is overly restrictive. Congress may have intended to limit courts to the nine narrow categories in the definition dealing with specially commissioned works.[144] However, this position stands on the assumption that Congress presumed itself to be qualified to determine which types of artists are more deserving of retaining the copyright to their works than others. This assumption contradicts the long standing policy that an original work need not be one of aesthetic merit or receiving critical acclaim to be copyrightable.[145] Anyone with an original work of au-

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139. *See* Aldon Accessories Ltd. v. Spiegel, Inc., 738 F.2d 548, 552 (2d Cir.), *cert. denied*, 469 U.S. 982 (1984).

140. H.R. REP. No. 1476, 94th Cong., 2d Sess. 121, *reprinted in* 1976 U.S. CODE CONG. & ADMIN. NEWS 5659, 5737.

141. 17 U.S.C. § 201(b) (1982).

142. *Id.* § 101.

143. *See supra* notes 32-51 and accompanying text.

144. 17 U.S.C. § 101 (1982).

145. *See* comments accompanying 17 U.S.C. § 102 (1982), H.R. REP. No. 1476,

thorship can protect that idea with a copyright by producing it in some kind of tangible medium.[146]

Finally, when confronted with a case similar to *Aldon*,[147] a court employing the literal interpretation would reach an inequitable result. The literal view does not protect someone who commissions another to produce a work, exercises significant control over the person he hired to do the work, and makes substantial contributions to the final appearance of the work. As long as our society would label the hired individual an "artist" and the hiring individual a "businessman" or "merchant," the hiring party's contributions would be deemed insignificant under the literal interpretation.[148]

The literalist's remedy for a situation similar to *Aldon* would be to label the work a joint work.[149] However, treatment of a work as a joint work requires an intention of the parties that the work be treated as a joint work, which would mean the parties also would intend to be bound by the legal consequences that arise from such a characterization. One necessary consequence is that, because coowners of joint works are treated as tenants in common, each coowner must account to all the other coowners for any profits he earns from marketing that work.[150] This would be unfair to the party who took the financial risk of marketing the work.

C. *The* Aldon *Compromise*

The *Aldon* compromise makes the most sense of the three interpretations in light of the ambiguous nature of the 1976 Act arising from

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94th Cong., 2d Sess. 51, *reprinted in* 1976 U.S. CODE CONG. & ADMIN. NEWS 5659, 5664 ("This standard [of originality] does not include requirements of novelty, ingenuity, or aesthetic merit, and there is no intention to enlarge the standard of copyright protection to require them.").

146. This longstanding policy directly conflicts with the views of Mr. Irwin Karp who represented the Authors League of America in the debates on the copyright bill. Mr. Karp indicated his sentiment that one had to be recognized by society as an "artist" in order to have his or her work protected by copyright laws when he said: "It's tempting to get off into a debate with anybody who claims that a lawyer or an accountant or a businessman helped to write any work of art. That's a lot of baloney." PRELIMINARY DRAFT FOR REVISED U.S. COPYRIGHT LAW AND DISCUSSIONS AND COMMENTS ON THE DRAFT 255, 269 (1964), *reprinted in* 3 G. GROSSMAN, OMNIBUS COPYRIGHT REVISION LEGISLATIVE HISTORY 255, 269 (1976) [hereinafter *Preliminary Draft*].

147. Aldon Accessories Ltd. v. Spiegel, 738 F.2d 548 (2d Cir.), *cert. denied*, 469 U.S. 982 (1984). For a discussion of the facts in *Aldon*, see *supra* notes 95-107 and accompanying text.

148. *See* Comment, *Sufficiently Supervised Commissioned Workers*, *supra* note 3.

149. *See supra* note 131. A finding that a joint work existed was the result in Mister B Textiles v. Woodcrest Fabrics, Inc., 523 F. Supp. 21 (S.D.N.Y. 1981).

150. H.R. REP. No. 1476, 94th Cong., 2d Sess. 121, *reprinted in* 1976 U.S. CODE CONG. & ADMIN. NEWS 5659, 5736.

the Act's failure to define "employee." Although the actual control test requires courts to do more work, the test is more flexible in its approach. The actual control test allows courts more freedom in adjudicating fact situations, such as that in *Aldon*, not envisioned by Congress.

1. The Actual Control Test is More Consistent With Legislative History.—As the cases and commentaries suggest, all three views can cite to the legislative history of the 1976 Act for support.[151] However, excerpts from the legislative history also contradict each view. A more in-depth view of the legislative process leading up to the Act reveals that the actual control test is most consistent with the legislative history and the Act.

Research for purposes of revising the work made for hire doctrine began in 1958 with a study prepared by Borge Varmer at the request of the Senate Judiciary Committee's Subcommittee on Patents, Trademarks and Copyrights.[152] In addition to discussing the case history under the 1909 Act, other bills introduced in Congress and foreign copyright laws, the Varmer study summarized the basic issues that should be considered.[153]

The study divided works into two categories: the first is "works made for hire" and the second is "works prepared on special order or commission."[154] Varmer noted a difference in treatment by the courts of the employer-employee relationship and that of the parties to a contract for a commissioned product.[155] He said this difference in treatment extended into the area of statutory copyright law.[156] The rationale for this distinction between employees and independent contractors is "the premise that an employer generally gives more direction and exercises more control over the work of his employee than does a commissioner with respect to the work of an independent contractor."[157] This expla-

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151. *See supra* notes 111-12, 125-27 and accompanying text.

152. *Study No. 13*, *supra* note 29.

153. *Id.* at 143.

154. *Id.* The final law, however, grouped works prepared by employees and works prepared on special order or commission under the same general category, "works made for hire." 17 U.S.C. § 101 (1982). Whether this indicates Congressional intent to call some independent contractors employees or whether this categorization is a mere oversight is not evident. If Congress consciously grouped works prepared by employees with specially commissioned works under "works made for hire," this certainly would indicate that Congress acknowledged that, in some cases, independent contractors and employees might be indistinguishable.

155. *Study No. 13*, *supra* note 29, at 142.

156. However, the 1909 statute was sufficiently ambiguous for courts to extend the "works made for hire" doctrine to all works prepared on special order or commission by independent contractors. *See, e.g.*, Brattleboro Publishing Co. v. Winmill Publishing Co., 369 F.2d 565 (2d Cir. 1966).

157. *Study No. 13*, *supra* note 29, at 142.

nation lends support to the *Aldon* compromise which, in effect, held that once a contractor becomes sufficiently supervised, he is no longer independent, but rather is an employee of the commissioning party.

Varmer's recommendation for the language of the new statute is particularly noteworthy. He stated:

> Regardless of the substantive provisions finally adopted, it might be helpful to clarify the scope of the concept "works made for hire." A new definition might take the form of "works created by an employee within the scope of his employment." This would serve to make it clear that works created by an employee on his own initiative outside of his employment, are not included. If the employment-for-hire rule is not to extend to works created on commission at a fixed fee, the definition might further specify "employment on a salary basis."[158]

The final version of the statute incorporated only part of Varmer's recommendation. Subsection (1) of the works made for hire definition includes a "work prepared by an employee within the scope of his or her employment."[159] However, Congress did not add "on a salary basis" to the definition. Therefore, perhaps Congress recognized that there would be some situations in which the distinction between independent contractors and employees would be hazy and that, in some cases, independent contractors might cross the line and actually become employees. The addition of "on a salary basis" to the definition of employee would have supported the literalists' view.

The actual control test for determining what Congress meant by "employee" is also consistent with the pattern that emerged from the various versions of the bill. The 1976 Copyright Revision Act received several changes during the sixteen year drafting process.

The 1909 Act merely provided that "the word 'author' shall include an employer in the case of works made for hire."[160] The preliminary draft bill prepared by the Copyright Office in 1963 defined a work made for hire as "a work prepared by an employee within the scope of the duties of his employment, but not including a work made on special order or commission."[161] Objections to the draft, calling it excessively restrictive of the scope of the work for hire doctrine, led Congress to change the definition to include "a work prepared on special order or

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158. *Id.* at 141.

159. 17 U.S.C. § 101 (1982).

160. Copyright Act of 1909, § 62, Pub. L. No. 349, ch. 320, 35 Stat. 1075, 1088 (repealed & reenacted 1947). *See* Pub. L. No. 281, ch. 391, § 26, 61 Stat. 652, 660 (1947) (repealed 1976).

161. *Preliminary Draft*, *supra* note 146, at 15 n.11.

commission if the parties expressly agree in writing that it shall be considered a work made for hire.''[162] Subsequent revisions and discussions resulted in the present definition.[163]

Obviously, Congress attempted to reach a compromise between the employers and the artists. The pattern of these revisions does not reveal whether Congress intended to limit the work for hire doctrine or to expand it. Some commentators argue that the preliminary draft indicates that Congress intended to limit the scope of the doctrine and only made exceptions in certain situations where compelling objections were raised.[164] However, it is also logical to read the pattern of revisions as congressional intent to broaden the scope of the doctrine, which was too severely restricted by the definition first proposed by the Copyright Office.[165]

Furthermore, even if Congress did intend to limit the doctrine's application to independent contractors, the question concerning the scope of the definition of ''employee'' in section 101 remains open. Finding congressional intent to limit the work-for-hire doctrine with regard to independent contractors does not avoid the preliminary step of determining if a creator is an employee or an independent contractor.

2. The Actual Control Test is More Consistent With the Application of Agency Law.—The courts agree that agency law principles are authoritative when determining if an employment relationship exists.[166] The Restatement (Second) of Agency lists several factors, the presence of which may indicate that the relationship is that of employer and employee.[167] The first factor is the extent of control that may be exercised by the hiring party over the one doing the work.[168] The comments to the Restatement stress the importance of control over the worker.[169] Yet

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162. 1964 Revision Bill With Discussion and Comments 1, 31 (1964), *reprinted in* 4 G. Grossman, Omnibus Copyright Revision Legislative History (1976).

163. 17 U.S.C. § 101 (1982). See *supra* text accompanying note 18 for the text of the provision.

164. *See, e.g.*, Comment, *Sufficiently Supervised Commissioned Workers*, *supra* note 3, at 400.

165. *See supra* text accompanying note 161.

166. *See, e.g.*, Community for Creative Non-Violence v. Reid, 846 F.2d 1485 (D.C. Cir.), *cert. granted*, 109 S. Ct. 362 (1988); Easter Seal Soc'y for Crippled Children & Adults of La., Inc. v. Playboy Enters., 815 F.2d 323 (5th Cir. 1987), *cert. denied*, 108 S. Ct. 1280 (1988); Aldon Accessories Ltd. v. Spiegel, Inc., 738 F.2d 548 (2d Cir.), *cert. denied*, 469 U.S. 982 (1984).

167. Restatement (Second) of Agency § 220(2) (1958), *supra* note 50.

168. *Id.* § 220(2)(a).

169. *Id.* comment d (''control or right to control the physical conduct of the person giving service is important and in many situations is determinative''); *id.* comment e (''the important distinction is between service in which the actor's physical activities and his time are surrendered to the control of the master, and service under an agreement to accomplish results'').

the literalists dismiss the consideration of control if the worker is not on the employer's regular payroll.[170]

The problem of distinguishing an employee from an independent contractor is not unique to copyright law. Cases involving labor disputes parallel the problem faced by courts making work for hire determinations.

In *NLRB v. United Insurance Co. of America*,[171] the United States Supreme Court noted the difficulty in many cases of determining whether a person is an employee or an independent contractor.[172] In *United Insurance*, the Court deemed it necessary to apply the common law agency test, in addition to examining the legislative history, to determine if debit agents of United Insurance, whose jobs were to collect premiums from policy-holders, prevent lapsing of policies and occasionally sell new policies, were employees or independent contractors. The Court weighed factors for and against finding the existence of an employment relationship and concluded that the NLRB's decision that the debit agents were employees should stand. One important factor was a letter from the company's chairman of the board in which he warned the agents to follow company rules when engaging in company business.[173]

The factors listed in the Restatement (Second) of Agency also have been used to determine if an employment relationship exists in cases involving payment of employment taxes,[174] eligibility for employee retirement plans[175] and other employee benefits,[176] and for purposes of labor management agreements,[177] in addition to numerous cases involving tortious conduct of alleged independent contractors.[178] The extent to which the hiring party exercises supervision over the worker is a decisive factor in determining whether that worker is an employee. Thus, the actual control test cannot be dismissed as easily as the supporters of the literal view insist.

Although agency law considers the *right* to control as a factor to determine if an employment relationship exists (also the view of the conservatives), *actual* control, for purposes of copyright ownership, more

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170. *See, e.g.*, *Easter Seal*, 815 F.2d at 336; Comment, *Sufficiently Supervised Commissioned Workers*, *supra* note 3.

171. 390 U.S. 254 (1968).

172. *Id.* at 258.

173. *Id.* at 259-60.

174. Avis Rent A Car Sys., Inc. v. United States, 503 F.2d 423 (2d Cir. 1974).

175. D.P. Oil Corp. v. Mabe, 370 A.2d 554 (Md. App. 1977).

176. Todd v. Benal Concrete Constr. Co., 710 F.2d 481 (9th Cir. 1983) (employee fringe benefit trust funds), *cert. denied*, 465 U.S. 1022 (1984).

177. *See* Yellow Taxi Co. v. NLRB, 721 F.2d 366 (D.C. Cir. 1983); Seven-Up Bottling Co. v. NLRB, 506 F.2d 596 (1st Cir. 1974).

178. *See* Kelley v. Southern Pac. Co., 419 U.S. 318 (1974); Ward v. Atlantic Coast Line R.R., 362 U.S. 396 (1960); Baker v. Texas Pac. Ry. Co., 359 U.S. 227 (1959).

accurately reflects the identity of the true creator of a copyrightable work. Employers of artists who are on the employers' regular payrolls can support their copyright ownership with arguments that they provided the workers with various benefits available to regular employees and supplied the materials and workplace. The employer of one who is normally characterized as an independent contractor, however, at least should prove that he actually supervised the worker in the process of creating the work.

In copyright law, a more equitable rule vests copyright ownership in someone who took an active part in the creative process and denies copyright ownership to someone who had an unexercised right to control. This actual control requirement more consistently conforms with the goal of the framers of the Constitution which led to the provision protecting authors and inventors.[179] Additionally, use of the right to control test may lead some courts to assume a work for hire relationship exists merely because of an employer's veto rights over the final product.[180] If only veto rights were necessary to create a work for hire situation, virtually all works would become works for hire.

3. The Actual Control Test is Workable and Equitable.—Admittedly, the *Aldon* compromise requires courts to conduct a deeper inquiry. However, contrary to the opinion of those supporting the literal view,[181] the actual control test is workable. Granted, a court will have to do more than look at an employer's payroll to determine if the creator of the work in question is an employee. The actual control test, however, only requires the trier of fact to examine the nature of the relationship to determine if the alleged employer exercised a sufficient amount of control over the manner in which the artist created the work.[182]

The majority of cases decided under the literal interpretation actually would have been decided similarly using the actual control test. For example, in *Childers v. High Society Magazine, Inc.*,[183] which involved a photographer whose portrait photographs were copied without permission by the defendant,[184] the photographer clearly was not an employee of the actresses he photographed. The actresses exercised no control over

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179. U.S. CONST. art. I, § 8, cl. 8.

180. *See, e.g.*, Peregrine v. Lauren Corp., 601 F. Supp. 828 (D. Colo. 1985).

181. *See, e.g.*, Easter Seal Soc'y for Crippled Children & Adults of La., Inc. v. Playboy Enters., 815 F.2d 323, 333-34 (5th Cir. 1987), *cert. denied*, 108 S. Ct. 1280 (1988).

182. *See* Aldon Accessories Ltd. v. Speigel, Inc. 738 F.2d 548, 552 (2d Cir.), *cert. denied*, 469 U.S. 982 (1984).

183. 557 F. Supp. 978 (S.D.N.Y. 1983).

184. *See supra* notes 134-38 and accompanying text.

the manner in which he performed his work. In an almost identical case, *International Sygma Photo News, Inc. v. Globe International Inc.*,[185] the same district court that decided *Childers* employed the actual control test to reach the same result.[186] The court cited *Aldon* for the propositions that a "formal or regular relationship of employment is not a necessary condition for 'employee' status within the meaning of section 101" and that the extent of control exercised over the commissioned worker is determinative.[187]

The case of *Everts v. Arkham House Publishers, Inc.*,[188] decided under the literal interpretation, also would have had the same result under the *Aldon* actual control test. In *Everts*, a poet, whose poems the plaintiff wanted to publish, worked without the plaintiff's supervision.[189] A court using the *Aldon* test would easily have concluded that no work for hire situation existed.

Two other cases supporting the literal view which would receive the same result under the actual control test concerned architects. The first, *May v. Morganelli-Heumann & Associates*,[190] was decided under the 1909 Act. In dictum, however, the Ninth Circuit noted that the 1976 Act changed prior law, so that specially commissioned works subject to the work for hire doctrine were limited to the nine exclusive categories of works in the second part of the definition.[191] In the second case, *Meltzer v. Zoller*,[192] which was decided under the 1976 Act, a district court limited commissioned works falling under the doctrine to those in the nine categories listed in section 101(2). Because architectural drawings are not included in those categories, the court concluded that the designs at issue were not works made for hire.[193] A court applying the actual control test easily would reach the same result in both of these cases.

The reason that the architect cases would achieve similar results under the actual control test is that, as both courts noted, there is a custom in the architectural profession that when an architect prepares drawings for a construction project, the architect, not the commissioning party, retains ownership in the copyright to those drawings.[194] The custom arises both from the extensive regulation and licensing of architects and

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185. 616 F. Supp. 1153 (S.D.N.Y. 1985).
186. *Id.* at 1156.
187. *Id.*
188. 579 F. Supp. 145 (W.D. Wis. 1984).
189. *Id.* at 146-47.
190. 618 F.2d 1363 (9th Cir. 1980).
191. *Id.* at 1363 n.4.
192. 520 F. Supp. 847 (D. N.J. 1981).
193. *Id.* at 855.
194. *May*, 618 F.2d at 1365; *Meltzer*, 520 F. Supp. at 856.

because architects' works must abide by the standards of that profession. No one can contend seriously that laymen who hire architects would be able to control the manner in which the architects perform their work.[195]

Even the federal district court that decided the *Easter Seal* case[196] used the *Aldon* test to conclude that the work in question was not a work made for hire.[197] The Fifth Circuit, however, charged that the *Aldon* actual control test easily can become the right to control test.[198] If the actual control test could slip into the right to control test, this transformation would mark the return of a pre-1976 work made for hire doctrine.

To support the proposition that the right to control test could be revived, the Fifth Circuit pointed to *Evans Newton, Inc. v. Chicago Systems Software.*[199] The Seventh Circuit applied the *Aldon* test in *Evans* to find that a work for hire existed even though the circumstances less convincingly supported a finding of an employment relationship.

The dispute in *Evans* arose out of the alleged infringing use of the plaintiff's computer program. Evans Newton, Inc. ("ENI") developed a computerized recordkeeping system for educational institutions compatible with programmable calculators. ENI contacted Chicago Systems Software ("CSS") to adapt its educational management program to the new, rapid, low-cost, programmable microcomputers increasingly available to ENI's customers. ENI's president developed the idea for ENI's Computer Managed Instruction Program but needed CSS's expertise to adapt the program to a Commodore computer.[200]

CSS spent about 200 to 300 hours developing the program, demonstrated the program during an in-house training session and introduced the program to ENI's customers. The customers requested functional changes which CSS made.[201] In summary, although ENI's president thought of the idea for the computerized management instruction program, CSS developed the idea into a program compatible with the new programmable computers and responded to ENI's customers' requests.

When CSS began to market a competitive program resembling ENI's program, ENI sued for copyright infringement, alleging that the program

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195. Aitken, Hezen, Hoffman, Miller, P.C. v. Empire Constr. Co., 542 F. Supp. 252, 258 (D. Neb. 1982).

196. Easter Seal Soc'y for Crippled Children & Adults of La., Inc. v. Playboy Enters., 815 F.2d 323 (5th Cir. 1987), *cert. denied*, 108 S. Ct. 1280 (1988).

197. *Id.* at 333.

198. *Id.* at 334.

199. 793 F.2d 889 (7th Cir.), *cert. denied*, 479 U.S. 949 (1986), *cited in Easter Seal*, 815 F.2d at 334.

200. 793 F.2d at 891.

201. *Id.* at 891-92.

was a work made for hire.[202] The court, citing the *Aldon* actual control test, agreed with ENI.[203] The court did not use the right to control test as the court in *Easter Seal*[204] contended, but the court did apply the actual control test to a much more difficult fact situation than that in *Aldon*. The extent of control ENI exercised over creation of the program may have been insufficient. However, this is necessarily a question of fact to be determined by the trial court.

The *Easter Seal* court's prediction that the actual control test would evolve into the right to control test did materialize, however, in *Marshall v. Miles Laboratories, Inc.*[205] Although the facts clearly indicated that the plaintiff, Marshall, was a regular employee of Miles working within the scope of his employment, the court cited *Aldon* and *Evans* for the proposition that the employer's right to control or supervise the creation determines whether an employment relationship existed.[206]

Other cases, however, ran contrary to the Fifth Circuit's prediction that the right to control test would grow out of the actual control test. The case of *Brunswick Beacon, Inc. v. Schock-Hopchas Publishing Co.*[207] is an example of proper commitment to the actual control test set out in *Aldon*. This case concerned advertisements prepared and published by the plaintiff newspaper for the paper's customers. The same advertisements later appeared in defendant's newspaper.[208] The Fourth Circuit cited *Aldon* for the premise that "in some circumstances, temporary and transitory situations exist in which an employee of one may be regarded as an employee of another."[209] Because the court found no evidence that the advertisers supervised the manner in which the advertisements were prepared, the court concluded that no work made for hire situation existed.[210] Therefore, the plaintiff (the newspaper that prepared the advertisements) owned the copyright.

The copyright statute is in need of another revision. Commentators agree that the terms "employer" and "scope of employment" require some clarification concerning the meaning of the word "employee."[211]

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202. *Id.* at 892-93.

203. *Id.* at 894.

204. Easter Seal Soc'y for Crippled Children & Adults of La., Inc. v. Playboy Enters., 815 F.2d 323, 334 (5th Cir. 1987), *cert. denied*, 108 S. Ct. 1280 (1988).

205. 647 F. Supp. 1326 (N.D. Ind. 1986).

206. *Id.* at 1331.

207. 810 F.2d 410 (4th Cir. 1987).

208. *Id.* at 411.

209. *Id.* at 412.

210. *Id.*

211. *See, e.g.*, Levin, *Misinterpretation*, *supra* note 15; O'Meara, *Two Interpretations*, *supra* note 65; Comment, *Sufficiently Supervised Commissioned Workers*, supra note 3.

To protect those employers who participate in creating a copyrightable work, the legislature should incorporate the actual control test into the definition of works made for hire. This also would protect those employers who take the risk of investing in production and marketing of the copyrightable work. By requiring actual exercise of the right to control, the actual control test also would protect those freelance artists who retain their artistic freedom.

IV. Conclusion

Because of the harsh results for freelance artists arising from the conservative interpretation[212] of the 1976 Act, the conservative view appears to be approaching extinction. The literal interpretation, however, is still very much alive.[213] The Supreme Court finally hear a case this term concerning works made for hire under the 1976 Act.[214] The time is ripe for the Supreme Court to settle the dispute over the proper test to be used to arrive at congressional intent.

Although those advocating the literal interpretation of the 1976 Act criticize *Aldon*, their real complaint is with the statute. First, the literalists criticize the Second Circuit's interpretation of the statute. However, because the word "employer" was never defined, the actual control test is just as likely to reveal legislative intent as is the literal interpretation. Furthermore, the actual control test conforms with the common law of agency regarding the distinction between employees and independent contractors.

Second, the literalists criticize *Aldon* because they contend that the actual control test injures more freelance artists than those already affected by the Act. The large majority of cases decided under the literal interpretation, however, would receive the same ruling under the actual control test. In most cases, those who employ freelance artists to create artistic works exercise little, if any, control over the manner in which the freelancers create the works. In some cases, in fact, the freelancers create the works even before communicating with the buyers. In addition, the actual control test rewards those employers who invested time and money in the works.

Congress should clarify the works made for hire doctrine in the Copyright Act by providing a precise definition of the word "employee."

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212. *See, e.g.*, Peregrine v. Lauren Corp., 601 F. Supp. 828 (D. Colo. 1985); Town of Clarkstown v. Reeder, 566 F. Supp. 137 (S.D.N.Y. 1983).

213. *See, e.g.*, Community for Creative Non-Violence, Reid, 846 F.2d 1485 (D.C. Cir.), *cert. granted*, 109 S. Ct. 362 (1988); Easter Seal Soc'y for Crippled Children and Adults of La., Inc. v. Playboy Enters., 815 F.2d 323 (5th Cir. 1987), *cert. denied*, 108 S. Ct. 1280 (1988).

214. *Community for Creative Non-Violence*, 846 F.2d 1485.

If Congress intended only artists who receive a regular salary from the employers to be considered employees for purposes of the doctrine, then the Act should have provided for this intent. The more logical and equitable solution, however, would be to incorporate the actual control test into the definition of employee.

CATHERINE A. KLING

Addendum

The United States Supreme Court recently approved the analysis of the Courts of Appeals for the District of Columbia and the Fifth Circuits in determining whether a work is made for hire. *Community for Creative Non-Violence v. Reid*, No. 88-293, slip op. (U.S. June 5, 1989). The Court held that a person is determined to be an employee according to common law agency principles, referring to the Restatement (Second) of Agency 220. *Id.* at 19-20.

The Court properly rejected the notion that only formal, salaried employees are "employees" within section 101 of the Copyright Act. *Id.* at 11. However, in rejecting the actual control test, the Court ignored the Restatement's acknowledgment of the importance of the employer's control over the hired party. *See supra* note 169. The Court also overlooked the fact that the actual control test does not disturb the dichotomy of section 101 because it is merely a means of determining whether someone is, in fact, an employee within the meaning of section 101(1). Slip op. at 11. Furthermore, the Court's depreciation of the actual control test would mean that the copyright to works of certain groups such as university professors would belong to their employers, a questionable result.

By emphasizing the actual control exercised over an artist's work, a court is more likely to give credit where it belongs by rewarding all the parties whose input is reflected in the finished work.

Tort Liability for DPT Vaccine Injury and the Preemption Doctrine

Infectious childhood diseases claimed thousands of lives annually in the United States before mass immunization brought the spread of communicable diseases under control. Today, vaccination of infants and young children is routine, and diseases such as pertussis, once a major cause of childhood mortality, are uncommon.[1] The development of vaccines to combat pertussis and other contagious diseases paralleled the growth of the administrative state during the 1930's and 1940's. The federal government, recognizing the national dimensions of disease control and the public health interest in safe and effective vaccines, implemented a regulatory scheme in 1944 which required licensure of all vaccine products and manufacturing facilities.[2] Today, the Food and Drug Administration (FDA) is responsible for determining safety standards in the vaccine industry.

The FDA licenses only one form of pertussis vaccine, which is administered routinely to young children as part of a three-in-one vaccination program. The FDA-approved DPT vaccine combines three different antigens to provide protection against diphtheria ("D"), pertussis ("P"), and tetanus ("T"). Despite consistent FDA approval, DPT vaccine has become the subject of controversy in recent years due to increased public awareness of the possibility of serious adverse reactions linked to the pertussis component. Although alternative types of pertussis vaccine currently are available in other countries, manufacturers are not permitted to distribute these vaccines in the United States because they do not satisfy federal standards for safety and efficacy. Even though the medical community continues to recommend routine vaccination to avoid the great public health risks of pertussis disease, some children inevitably will suffer severe brain damage or death as a result of the inoculation.[3]

When a vaccine-related injury occurs, a lawsuit against the manufacturer often follows because many of these children are unable to pay for their medical and rehabilitative needs.[4] Tort plaintiffs claim that

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1. Cherry, *The Epidemiology of Pertussis and Pertussis Immunization in the United Kingdom and the United States: A Comparative Study*, 14 CURRENT PROBLEMS IN PEDIATRICS 7 (1984).

2. Public Health Service Act, Pub. L. No. 78-410, 58 Stat. 682 (1944) (codified as amended at 42 U.S.C. §§ 201-405 (1982)).

3. Peter, *Vaccine Crisis: An Emerging Societal Problem*, 151 J. OF INFECTIOUS DISEASE 981 (1985).

4. H.R. REP. No. 908, 99th Cong., 2d Sess. 4, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS 6344, 6345.

safer pertussis vaccines are feasible. Manufacturers, however, cannot distribute an alternative pertussis vaccine without violating current FDA regulations[5] and, therefore, are confronted with skyrocketing litigation costs which threaten to render continued production of pertussis vaccine unprofitable. The withdrawal of this vaccine from the market could result in a substantial public health problem, and pertussis disease once again could reach epidemic proportions. Manufacturers, thus, are faced with a dilemma: should they stop producing the only approved vaccine to avoid huge tort judgments, or should they violate federal law by attempting to distribute an unlicensed vaccine which may be as effective but cause fewer or less severe reactions than the licensed variety. This dilemma stems from an inherent conflict between the federal regulatory system and state tort law in the area of vaccine regulation.

Products liability law has developed in piecemeal fashion under state common law and state statutory reform, resulting in a system of litigation filled with uncertainties.[6] Litigation costs and inconsistent results have led vaccine manufacturers to seek preclusion, or preemption, of tort liability for DPT-related injuries on the theory that damage awards are incompatible with the mandates and objectives of the federal regulatory scheme. They argue that there is an inherent conflict between federal regulations which mandate one vaccine design and state tort judgments holding manufacturers liable for producing that vaccine according to federal specifications.

Under the Supremacy Clause of the United States Constitution,[7] federal law can preclude concurrent state regulation in appropriate situations. The preemption doctrine defines the boundaries of state power in relation to federal power. Its guiding principle is to promote the legitimate exercise of federal power without expanding that power at the expense of legitimate state interests. The scope of the federal law's preemptive effect, therefore, depends upon the subject regulated and the degree to which state and federal law conflict.

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5. 21 U.S.C. §§ 331(d), 333(a), 355(a) (1982). *See also* Toner v. Lederle Laboratories, 779 F.2d 1429, 1431 (9th Cir. 1986).

6. Reed & Watkins, *Product Liability Tort Reform: The Case for Federal Action*, 63 NEB. L. REV. 389, 394-95 (1984). *See also* Burke, *DPT Vaccine Controversy: An Assessment of the Liabilities of Manufacturers and Administering Physicians Under Several Legal Theories*, 17 SETON HALL 541 (1987).

7. The Supremacy Clause provides:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

U.S. CONST. art. VI, cl. 2.

Recent shortages of DPT vaccine resulting from manufacturers' reluctance to stay in the vaccine business[8] have prompted the federal government to take action. In 1986, Congress enacted a program designed to limit manufacturers' liability, provide no-fault compensation to vaccine-injured persons, promote immunization, and encourage the development of safer vaccines. The two-fold purpose of the National Childhood Vaccine Injury Act of 1986[9] (Vaccine Act) was to provide a new federal remedy and to ensure an uninterrupted supply of vaccines to meet federal immunization initiatives.[10]

The provisions of the Vaccine Act were not immediately operative, however, because Congress failed to fund the compensation program at that time.[11] With the national focus on reduced spending and a balanced federal budget, Congress was reluctant to appropriate the substantial amount necessary to fund no-fault compensation for vaccine-related injuries.[12] In addition, the Reagan administration opposed the compensation structure enacted by Congress and threatened to reject any funding measure until certain deficiencies in the program were corrected.[13]

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8. Reitze, *Federal Compensation for Vaccination Induced Injuries*, 13 B.C. ENVTL. AFF. L. REV. 169, 194 (1986).

9. Pub. L. No. 99-660, 100 Stat. 3784 (codified as amended at 42 U.S.C. §§ 300aa-1 to 300aa-33 (Supp. IV 1986)).

10. H.R. REP. No. 908, 99th Cong., 2d Sess. 3-5, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS 6344, 6344-46. *See also* Patten v. Lederle Laboratories, 655 F. Supp. 745, 749 (D. Utah 1987).

11. The Act provided that subtitle 2 (the vaccine compensation program) "shall take effect on the effective date of a tax enacted after the date of the enactment of this Act to provide funds for compensation paid under such subtitle 2." Pub. L. No. 99-660, tit. III, part B, § 323(a), 100 Stat. 3743, 3784 (1986).

12. It was estimated that an initial appropriation of $40 million would be required to establish the compensation fund which would be repayable to the federal treasury from excise taxes on future vaccine sales. H.R. REP. No. 908, 99th Cong., 2d Sess. 33-34, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS 6344, 6374-75. Adequate tax rates, however, necessarily depend upon reasonably accurate predictions of the number and amount of claims. If future claims and operating costs are underestimated, additional annual appropriations would be necessary to offset resulting deficits in the fund. *Funding Mechanisms for the National Childhood Vaccine Injury Program: Hearings Before the Subcomm. on Select Revenue Measures of the House Comm. on Ways and Means*, 100th Cong., 1st Sess. 19-20 (1987) (statement of Dennis Ross, Tax Legislative Counsel, Department of Treasury).

13. The Vaccine Act was part of comprehensive public health legislation which President Reagan signed into law primarily because other parts of the legislation were deemed important to the national economy and also because the vaccine program would not take effect immediately. The President expressed his opposition to imposing any additional burdens on the American taxpayer and further objected to certain aspects of the structure and administration of the compensation program. 22 WEEKLY COMP. PRES. DOC. 1565-66 (Nov. 14, 1986).

An apparent compromise was reached in the 1987 Vaccine Amendments which were passed as part of the Omnibus Budget Reconciliation Act of 1987.[14] Congress modified certain administrative aspects of the program and provided funding on a limited basis. Annual appropriations of $80 million from 1989 to 1992 are provided to compensate persons injured before October 1, 1988, the effective date of the program.[15] Compensation for vaccine-related injuries or death on or after the effective date is to be paid from the new Vaccine Injury Compensation Trust Fund with revenues raised from an excise tax on vaccine sales between January 1, 1988 and December 31, 1992.[16] However, both funding mechanisms may be terminated before the end of 1992. If the annual appropriations from the general fund are insufficient, the only recourse for persons injured before the effective date is through civil actions for damages.[17] The Trust Fund program will terminate if the number of awards in a certain period of time exceeds the maximum number specified for that period.[18] The purpose of these limitations is to insure the solvency of the compensation program without creating an unfair excise tax burden.[19] The consequence is that the federal vaccine compensation program has eased, but not eliminated, the liability crisis. Civil actions remain available under the program, with certain restrictions, and are the only recourse if the program is terminated.

In addition to the Vaccine Act's potential impact on the liability of vaccine manufacturers, the Act itself has become an issue in the preemption debate. DPT plaintiffs maintain that the Act's structure and legislative history clearly evidence a congressional understanding that tort claims arising prior to the Act's effective date are not preempted. Their opponents argue that the Act's provisions do not alter the preemptive effect of regulations promulgated under prior federal statutes.

This Note examines the preemptive effect of federal vaccine regulation on state tort law. Part I reviews the nature of pertussis, pertussis vaccines and national immunization policies.[20] Part II explores various theories of products liability and the inadequacy of tort law in dealing with problems related to vaccine injury.[21] Part III applies a framework of

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14. Pub. L. No. 100-203, §§ 4301-07, 9201-02, 101 Stat. 1330-221 to -225, 1330-327 to -331.

15. 42 U.S.C.A. § 300aa-15(j) (West Supp. 1988).

16. *Id.* § 300aa-15(i) and 26 U.S.C.A. §§ 4131-32, 9510 (West Supp. 1988).

17. 42 U.S.C. § 300aa-15(f) (Supp. IV 1986).

18. 42 U.S.C.A. § 300aa-34 (West Supp. 1988).

19. H.R. REP. No. 391(II), 100th Cong., 1st Sess. 1023, *reprinted in* 1987 U.S. CODE CONG. & ADMIN. NEWS 2313-1, 2313-640.

20. *See infra* notes 24-104 and accompanying text.

21. *See infra* notes 105-170 and accompanying text.

preemption analysis to the circumstances surrounding vaccine litigation and explores the significance of the amended Vaccine Act in the preemption debate.[22] Part IV concludes that the Act does not alter the prior limited preemptive effect of federal vaccine regulation and immunization policies.[23] State tort law is preempted by federal regulations on the narrow issue of strict liability for design defect. Other aspects of tort liability for vaccine-related injuries are not preempted by the federal regulatory scheme.

I. DPT Vaccine and Federal Regulations

A. Pertussis Disease

Pertussis, or whooping cough, is a highly contagious respiratory disease transmitted when droplets containing the *Bordetella pertussis* bacterial organism are expelled from an infected person's respiratory tract into the air.[24] Young children are most susceptible to the bacterium and often suffer from acute respiratory infections which trigger sudden episodes of violent coughing followed by high-pitched whoops as the air is forcefully inhaled.[25] The disease progresses from a preliminary stage with symptoms resembling those of the common cold,[26] through the whooping stage, and finally to a convalescent stage in which the coughing spells gradually subside.[27]

Pertussis is a relatively benign disease, and the only treatment is supportive in nature.[28] Recovery may take many weeks or months, but with proper care most patients survive the disease if there are no com-

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22. *See infra* notes 171-299 and accompanying text.

23. *See infra* text accompanying note 300.

24. American Academy of Pediatrics, Report of the Committee on Infectious Diseases 267 (20th ed. 1986) [hereinafter Red Book]. This official publication of the AAP is commonly known as the "Red Book."

25. Feigin, *Pertussis (Whooping Cough)*, in K. Nelson, Textbook on Pediatrics 658, 660 (R. Behram & V. Vaughan eds. 12th ed. 1983).

26. Symptoms in this "catarrhal" stage include sneezing, watery eyes, dry cough, hoarseness, loss of appetite, and sometimes a low-grade fever. *See* Feigin, *supra* note 25, at 659-60; Grossman & Jawetz, *Infectious Diseases: Bacterial*, in Current Medical Diagnosis and Treatment 859 (M. Krupp & M. Chatton eds. 1984).

27. During the whooping, or "paroxysmal," stage, episodes of severe coughing continue until the child is able to dislodge the mucous plug obstructing the airway. Symptoms associated with these episodes include facial redness, bulging eyes, salivation, distention of the neck veins, vomiting, and exhaustion. *See* Feigin, *supra* note 25, at 660; Grossman & Jawetz, *supra* note 26, at 859.

28. Treatment includes maintenance of hydration and nutrition, respiratory care, and precautions to avoid provoking coughing attacks. Feigin, *supra* note 25, at 661.

plications.[29] The danger lies in the complications which often accompany pertussis, including secondary infections such as pneumonia, seizures, apneic episodes, and encephalopathy.[30] Encephalopathy, or inflammation of the brain tissue, can result in severe alterations of consciousness and permanent neurologic deficits.[31]

Pertussis was a major cause of childhood mortality in the United States before vaccination programs became prevalent. The country's worst pertussis epidemic occurred in 1934 when there were more than a quarter of a million reported cases of the disease and more than seven thousand related deaths.[32] Although the incidence of pertussis cases began to decline in the late 1930's as medical care in general improved, the annual mortality rate among young children remained high.[33] A recent study reported that "[d]uring the first year of life more deaths resulted from pertussis than measles, scarlet fever, diphtheria, poliomyelitis, and meningitis combined during the period 1940-1948."[34] As vaccination against pertussis became more prevalent in the late 1940's and early 1950's, the incidence of the disease declined dramatically from 109.1 reported cases per 100,000 population in 1943-1945 to 33.5 per 100,000 population in 1953-1955.[35] Over the next twenty-five years, vaccination programs were implemented nationwide. By 1981, the rate was down to 0.54 cases per 100,000 population due to widespread immunization of infants and young children and scientific advances in vaccine research.[36] In 1985, approximately ninety percent of the children in the United States received adequate immunization against pertussis.[37]

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29. *Id. See also* Grossman & Jawetz, *supra* note 26, at 860.

30. RED BOOK, *supra* note 24, at 266. *See also* Feigin, *supra* note 25, at 660; Manclark & Cowell, *Pertussis*, in BACTERIAL VACCINES 69-106 (Germanier ed. 1984).

31. RED BOOK, *supra* note 24, at 272. The Vaccine Act defines encephalopathy as "any significant acquired abnormality of, or injury to, or impairment of function of the brain." 42 U.S.C. § 300aa-14(b)(3)(A) (Supp. IV 1986).

32. There were 265,269 cases with 7,518 deaths reported. Hinman & Koplan, *Pertussis and Pertussis Vaccine: Reanalysis of Benefits, Risks, and Costs*, 251 J. OF THE AM. MED. A. 3109 (1984). *See also* Brief for the United States as Amicus Curiae on Behalf of the Department of Health and Human Services at 9, Abbot v. American Cyanamid Co., 844 F.2d 1108 (4th Cir. 1988) [hereinafter U.S. Brief].

33. David, *DTP: Drug Manufacturer's Liability in Vaccine-Related Injuries*, 9 J. PROD. LIAB. 361, 365 (1986). *See also* Cherry, *supra* note 1, at 33.

34. Cherry, *supra* note 1, at 18.

35. Pittman, *The Concept of Pertussis as a Toxin-Mediated Disease*, 3 PEDIATRIC INFECTIOUS DISEASE 467, 468 (1984). Dr. Pittman developed the potency and toxicity tests for pertussis vaccine adopted by the various public health agencies and in 1984 was associated with the Center for Drugs and Biologics of the Food and Drug Administration.

36. *Id.*

37. Peter, *supra* note 3, at 981.

Although pertussis cases are now rare, the disease continues to claim victims[38] and the potential for epidemics remains.[39] The true incidence of the disease may never be known. Cases still go unreported, either because the disease is difficult to identify from clinical symptoms or because routine diagnostic laboratory tests do not isolate the responsible organism.[40] The Centers for Disease Control (CDC)[41] estimate that there would be approximately 322,000 additional cases of the disease and 450 deaths per year without the current pertussis vaccination program.[42]

B. DPT Vaccine: Benefits and Risks

In 1906, scientists at the Pasteur Institute in Brussels identified the *Bordetella pertussis* bacterium as the cause of whooping cough.[43] Further research led to the development of experimental vaccines made from whole killed cells of the bacterial agent, and clinical trials in the 1930's demonstrated their effectiveness.[44] Scientists acknowledged that the organisms could trigger occasional severe reactions, but they were unable to distinguish and separate the immunizing factors from the components responsible for adverse reactions.[45] In 1944, the Council on Pharmacy and Chemistry of the American Medical Association endorsed pertussis vaccination despite its risks in order to combat the greater threat of pertussis disease.[46]

The federal government subsequently licensed a combined vaccine consisting of diphtheria toxoids, tetanus toxoids and the whole-cell pertussis component which became known as DPT vaccine.[47] Federal criteria for potency testing of all batches of the vaccine and criteria governing

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38. Approximately ten deaths per year are attributed to pertussis. *Recommendation of the Immunization Practices Advisory Committee (ACIP): Diptheria, Tetanus, and Pertussis: Guidelines for Vaccine Prophylaxis and Other Preventive Measures*, 34 MORBIDITY AND MORTALITY WEEKLY REP. 405, 406 (1985) [hereinafter *ACIP-DPT Guidelines*].

39. Hinman & Koplan, *supra* note 32, at 3113. *See also* Peter, *supra* note 3, at 982.

40. Serologic testing is not feasible in routine laboratory diagnostic tests. *See* Hinman & Koplan, *supra* note 32, at 3109.

41. The United States Public Health Service established the CDC in 1973 to provide guidance in the prevention and control of diseases and to respond to public health emergencies. The agency provides consultation and assistance to local health authorities and conducts a national program of research and education. It also consults with other nations concerning the control of communicable diseases.

42. Hinman & Koplan, *supra* note 32, at 3112.

43. U.S. Brief, *supra* note 32, at 6.

44. Cherry, *supra* note 1, at 29.

45. *See* Pittman, *supra* note 35, at 468.

46. Cherry, *supra* note 1, at 32.

47. U.S. Brief, *supra* note 32, at 7. *See also* Cherry, *supra* note 1, at 32. Some commentators prefer the acronym "DTP".

the manufacturing process were promulgated at that time. Each component of the vaccine triggers the body's production of antibodies to protect against the three target diseases. The diphtheria and tetanus components consist of modified bacterial toxins called toxoids. Unlike the whole-cell pertussis components, the immunizing factors in toxoids can be identified, extracted and purified, while the offending elements are separated out. This purification process virtually eliminates the pathogenicity of toxoids, so serious reactions to the diphtheria and tetanus components are extremely rare. Consequently, reactions to DPT vaccine generally are attributed to the pertussis component.[48] The most common reactions involve local pain or swelling with no serious consequences. Severe reactions are rare but may result in permanent neurological damage or death.[49]

Evaluating the frequency and relative severity of reactions to DPT vaccine is difficult due to under-reporting. In most states, private physicians are not required to report adverse reactions.[50] Public health clinics must notify the CDC of adverse reactions, but they rely on voluntary reporting by parents.[51] In addition, there are no comprehensive and scientifically reliable clinical studies of DPT vaccine reactions. The only large-scale study in this country[52] has been widely criticized[53] for flaws inherent in the data-gathering process, which resulted in significantly underestimated risks for certain groups of children.

The American Academy of Pediatrics and the CDC, relying on the results of a British study,[54] estimate that the risk of permanent neurologic

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48. *See* Toner v. Lederle Laboratories, 779 F.2d 1429, 1430 (9th Cir. 1986); Preiser, *Preparation of a DPT Vaccine Case*, 7 TRIAL DIPL. J. 10 (1984).

49. STAFF OF THE SUBCOMM. ON HEALTH AND THE ENV'T OF THE HOUSE COMM. ON ENERGY AND COMMERCE, 99TH CONG., 2D SESS., CHILDHOOD IMMUNIZATIONS 24-29 (Comm. Print 99-LL 1986) [hereinafter *Childhood Immunizations*]. *See also* H.R. REP. No. 908, 99th Cong., 2d Sess. 6, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS 6344, 6346-47.

50. Reitze, *supra* note 8, at 189. In 1984, Maryland became a leader in vaccine reform, enacting legislation which requires health care providers to record and report severe DPT reactions. *See* MD. HEALTH-GEN. CODE ANN. § 18-330(b) (1987).

51. Reitze, *supra* note 8, at 189.

52. The UCLA School of Medicine conducted a federally funded study in 1978 and 1979. *See* Cody, Baraff, Cherry, Marcy & Manclark, *Nature and Rate of Adverse Reactions Associated with DPT and DT Immunizations in Infants and Young Children*, 68 PEDIATRICS 650 (1981).

53. *See, e.g.*, Preiser, *supra* note 48, at 12; Reitze, *supra* note 8, at 190-91.

54. Aldersade, Bellman & Rawson, *The National Childhood Encephalopathy Study* in WHOOPING COUGH: REPORTS FROM THE COMMITTEE ON SAFETY OF MEDICINES AND THE JOINT COMMITTEE ON VACCINATION AND IMMUNIZATION (London, Department of Health and Social Security, Her Majesty's Stationery Office, 1981). *See also* David, *supra* note 33, at 371-72.

damage is one in 310,000 doses of DPT.[55] The CDC, however, has questioned whether the British methods may have either overestimated or underestimated the frequency of serious complications.[56] In addition, the British results do not necessarily reflect the risks in this country because the British vaccine has a much lower potency than the only vaccine licensed for use in the United States.[57]

Although the extent and severity of reactions to DPT vaccine remain uncertain, these events cannot be eliminated entirely under the present state of the art.[58] The medical community recognizes that there will always be victims but nevertheless promotes a policy of widespread immunization because the benefits of vaccination against pertussis outweigh the risks.[59] This view is supported by recent experiences in the United Kingdom[60] and Japan,[61] where pertussis epidemics occurred after public concern for vaccine damage led to a significant decline in vaccination rates.

Dr. James D. Cherry analyzed the British experience and predicted that the attack rate of pertussis in the United States would increase by a factor of 178 without immunization.[62] Although both the disease and vaccine may cause permanent neurological damage, Dr. Cherry concluded

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55. *Vaccine Injury Compensation: Hearings on H.R. 5810 Before the Subcomm. on Health and the Env't of the House Comm. on Energy and Commerce*, 98th Cong., 2d Sess. 73 (1984) (statement of Edward Brandt, Jr., M.D., Ass't Sec. for Health) [hereinafter *1984 Vaccine Hearings*].

56. Hinman, *The Pertussis Vaccine Controversy*, 99 PUB. HEALTH REP. 255, 257 (1984).

57. Reitze, *supra* note 8, at 190.

58. *1984 Vaccine Hearings*, *supra* note 55, at 140 (statement of Alan Nelson, M.D., American Medical Association).

59. Hinman & Koplan, *supra* note 32, at 3110-12. *See also* RED BOOK, *supra* note 24, at 269. Even when contraindications are present, the AAP recommends that pertussis immunization be reconsidered at each subsequent medical visit. *Id.* at 274.

60. Hinman & Koplan, *supra* note 32, at 3109. Epidemics occurred from 1977 to 1979 and again in 1982 in the United Kingdom after the dangers of pertussis vaccine were publicized by the media in 1974. Similar publicity aroused the American public's awareness in 1982 when a program highlighting the risks of pertussis vaccination was broadcast nationally. *Id.* at 3110-11.

61. DPT vaccination was discontinued for a few months in 1975 and then reinstated by the Japanese Ministry of Health and Welfare, but public confidence in the vaccine had been shaken. Kanai, *Japan's Experience in Pertussis Epidemiology and Vaccination in the Past Thirty Years*, 33 JAPAN J. MED. SCI. & BIOLOGY 107, 112 (1980). In the preceding five-year period, there were 1,887 reported cases and 15 deaths attributed to pertussis. With the decline of the vaccination rate, there were 31,730 reported cases and 118 deaths between 1974 and 1979. *Id.* at 109. *See also* David, *supra* note 33, at 373.

62. Cherry, *supra* note 1, at 68. Dr. Cherry is Professor of Pediatrics and Chief of the Division of Infectious Diseases at the Center for the Health Sciences, University of California at Los Angeles.

that the danger of such complications would be four times greater without vaccination.[63] In 1984, Dr. Alan R. Hinman and Dr. Jeffrey P. Koplan of the CDC added the cost factor to the risk-benefit analysis. They found that pertussis vaccination results in a substantial economic benefit in addition to the primary benefit of disease reduction.[64]

These studies have convinced the Immunization Practices Advisory Committee (ACIP) of the CDC to recommend the continued use of whole-cell pertussis vaccine despite reports of adverse reactions.[65] The Red Book Committee of the American Academy of Pediatrics supports this conclusion.[66] Both groups recommend immunization of all young children unless further pertussis vaccination is contraindicated by previous reactions to the vaccine. Contraindications include allergic hypersensitivity, high fever, convulsions, collapse, prolonged unconsolable crying or screaming episodes, and encephalopathy.[67]

A successful immunization program depends on vaccination of a high percentage of the target population. Infants and young children are most susceptible to pertussis, and mortality is greatest in infants

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63. The risk of seizure may be slightly less without pertussis vaccination, but the benefit/risk ratios of immunization for pneumonia, hospitalization, and death are 38:1, 21:1, and 19:1 respectively. *Id.*

64. Although pertussis vaccine may produce more cases of neurological damage than the disease, a vaccination program would reduce both the incidence of the disease and disease-related costs, such as hospitalization, by 90%. After factoring in the costs of administering a vaccination program, the benefit/cost ratio is 11.1:1. Hinman & Kolplan, *supra* note 32, at 3110-12. Drs. Hinman and Koplan are associated with the Division of Immunization, Centers for Disease Control.

65. *ACIP-DPT Guidelines*, *supra* note 38, at 407-08. The acronym ACIP is based on the Committee's former name, the Advisory Committee on Immunization Practices. The Committee, a group of medical specialists in the field of vaccines, was formed in the 1960's by the United States Public Health Service to advise the Surgeon General on immunization policy. It issues periodic recommendations to public and private health care providers through the CDC's official information publication, *Morbidity and Mortality Weekly Report*. The controversy over publicized reports of serious reactions to DPT prompted a formal reevaluation by the ACIP. It reported that certain children should not receive the vaccine for medical reasons and identified specific reactions and symptoms that contraindicate further immunization. The ACIP concluded, however, that "the benefits of the vaccine continue to outweigh its risks." *Id.* at 407.

66. Red Book, *supra* note 24, at 269-72. The *Red Book* is the standard used by private physicians, whereas the recommendations of the ACIP are directed primarily at public health clinics. Despite some minor differences, the two groups maintain liaison with each other to ensure overall consistency in their guidelines. *Immunization and Preventive Medicine, 1982: Hearings Before the Subcomm. on Investigations and General Oversight of the Senate Comm. on Labor and Human Resources*, 97th Cong., 2d Sess. 9 (1982) (statement by Dr. William H. Foege, Dir. of Centers for Disease Control).

67. 43 Physicians Desk Reference 1154 (1989). *See also* Reitze, *supra* note 8, at 192-93.

under one year of age.[68] The recommended vaccination schedule begins at two months and includes three doses before the child is two years old, with a booster at four to six years of age before the child enters school.[69] Vaccination is not recommended for children over six because they are less susceptible and the disease is relatively mild in older individuals.[70] Any central nervous system reaction contraindicates further injections of the combined DPT vaccine, and subsequent immunization is limited to a DT vaccine without the pertussis component.[71]

In most states, DPT vaccination is compulsory before a child may attend public school,[72] but immunization requirements vary from state to state. The standard exception is a physician's determination that vaccination may seriously impair a child's health. Many states also provide an exemption for religious objections, and some permit parents to object on the ground of "personal conviction" or "philosophical objection."[73] Policy concerns for public health, however, may outweigh the reasons for permitting religious or philosophical exceptions. Some states, therefore, limit exemptions to children with medical contraindications.

Compulsory vaccination has been upheld as a valid exercise of a state's police power.[74] Some members of the vaccinated population do not achieve complete immunity and are, therefore, at risk when exposed to children who have not been vaccinated. In 1979, the Mississippi Supreme Court held that a statutory religious exemption violated the fourteenth amendment rights of the majority of school children who were vaccinated by exposing them to the risk of contagious disease carried by those exempted.[75]

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68. Feigin, *supra* note 25, at 659.

69. Grossman & Jawetz, *Introduction to Infectious Diseases*, in CURRENT MEDICAL DIAGNOSIS AND TREATMENT 831 (M. Krupp & M. Chatton eds. 1984).

70. Grossman & Jawetz, *supra* note 26, at 859.

71. *Recommendation of the Immunization Practices Advisory Committee (ACIP): Supplementary Statement of Contraindications to Receipt of Pertussis Vaccine*, 33 MORBIDITY AND MORTALITY WEEKLY REP. 169 (1984).

72. Forty states required pertussis vaccination for the 1985-86 school year. CENTERS FOR DISEASE CONTROL, STATE IMMUNIZATION REQUIREMENTS (1986). In Hurley v. Lederle Laboratories, 651 F. Supp. 993 (E.D. Tex. 1986), *rev'd*, 851 F.2d 1536 (5th Cir. 1988), the court noted that all but nine of fifty-two jurisdictions (District of Columbia, Puerto Rico, and all fifty states) required pertussis immunization before school entry, and four of the nine recommended it. *Id.* at 996.

73. CENTERS FOR DISEASE CONTROL, STATE IMMUNIZATION REQUIREMENTS (1986). *See also* DISSATISFIED PARENTS TOGETHER, PERTUSSIS VACCINE: INFORMATION FOR PARENTS (1983). *See infra* note 85 and accompanying text.

74. Jacobson v. Massachusetts, 197 U.S. 11 (1905).

75. Brown v. Stone, 378 So. 2d 218 (Miss. 1979). *See also* Cude v. State, 377 S.W.2d 816 (Ark. 1964) (religious freedom does not include the right to expose others to communicable disease or death).

The federal government strongly encourages state vaccination programs as part of a national policy to combat serious childhood diseases. The Vaccination Assistance Act of 1962[76] established an aggressive program to protect the population against four target diseases: poliomyelitis, diphtheria, tetanus, and pertussis. Congress recognized the public health hazard created by incomplete vaccination[77] and appropriated funds to assist local health authorities carry out their vaccination programs.

The Act expired in 1968, with a resulting drop in immunization levels and corresponding increase in the incidence of the four targeted diseases. Congress responded with the Communicable Disease Control Amendments of 1970[78] and additional appropriations for immunization programs in 1972, 1976, 1981, and 1984.[79] In 1972, the Senate Committee on Labor and Public Welfare stated: "The Committee believes it is imperative that the federal government play a leadership role in providing a consistent and coordinated plan to prevent and control communicable diseases."[80] A House committee recommended extension of the federal initiative in 1982, noting the federal objective to raise immunization levels against the targeted diseases and to "establish a permanent system to provide comprehensive immunization services to more than three million children born in the United States each year."[81]

Congress declined to include measles in the 1962 Act because the reliability and safety of existing measles vaccines were in doubt.[82] That

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76. Pub. L. No. 87-868, 76 Stat. 1155.

77. A House report observed:

> The Committee is convinced on the basis of the testimony which it received that intensive community vaccination programs are required if the threat of epidemics of these diseases is to be wiped out. . . . [T]he failure to administer the vaccine to substantially all of the population in the United States constitutes a continuing public health threat. The threat of epidemics of these diseases can be avoided and therefore the continuing threat constitutes a totally unnecessary risk.

H.R. REP. No. 1835, 87th Cong., 2d Sess. 3 (1962). *See also* S. REP. No. 1907, 87th Cong., 2d Sess. 9, *reprinted in* 1962 U.S. CODE CONG. & ADMIN. NEWS 3970, 3971.

78. Pub. L. No. 91-464, 84 Stat. 988.

79. Communicable Disease Control Amendments Act of 1972, Pub. L. No. 92-449, 86 Stat. 988; Disease Control Amendments of 1976, Pub. L. No. 94-317, 90 Stat. 700; Omnibus Budget Reconciliation Act of 1981, Pub. L. No. 97-35, § 928(b), 95 Stat. 357, 569; Preventative Health Amendments of 1984, Pub. L. No. 98-555, 98 Stat. 2854. Appropriations for recent years include: $52 million for the fiscal year ending Sept. 30, 1985; $59 million for the fiscal year ending Sept. 30, 1986; $65 million for the fiscal year ending Sept. 30, 1987. 42 U.S.C. § 247b(j)(1) (1982 & Supp. IV 1986).

80. S. REP. No. 825, 92d Cong., 2d Sess. 5-6, *reprinted in* 1972 U.S. CODE CONG. & ADMIN. NEWS 3430, 3436.

81. H.R. REP. No. 1063, 98th Cong., 2d Sess. 2 (1984).

82. *See* 108 CONG. REC. 3133 (1962) (statement of Senator Hill and letter from Secretary Ribicoff) (bill may be extended to apply to other diseases, such as measles, when more reliable vaccines become available).

pertussis has been included consistently is an indication that Congress deems the existing whole-cell pertussis vaccine to be sufficiently safe and reliable despite growing public concern about adverse reactions. In 1984, a Senate report reaffirmed this policy:

> With the authorization levels specified in its bill, the Committee intends to assure high levels of immunization, especially at a time of increasing costs for vaccines, and to provide support for D.P.T. vaccination programs. The Committee is also aware that there is growing concern about the safety of vaccine products.[83]

Ironically, the success of immunization programs also has contributed to increased public concern about vaccine reactions. Although the risks are not greater now than they were ten or twenty years ago, complications from the vaccine appear to be more prevalent because immunization programs have been so effective in reducing the occurrence of pertussis disease.

The American public's awareness of the risks associated with DPT vaccine was heightened in 1982 by a national television broadcast entitled "DPT: Vaccine Roulette."[84] The publicity resulted in the formation of a citizens lobby called Dissatisfied Parents Together.[85] These parents of children who have suffered adverse reactions challenge the federal government's position favoring widespread DPT immunization and lobby for laws that would limit vaccinations and permit parents to refuse vaccination.

If mass public participation in immunization programs is deterred by adverse publicity over-emphasizing the risks of vaccination and by efforts promoting the right to opt out, these programs could be seriously undermined. The experiences in the United Kingdom and Japan support the medical community's fear that a significant decrease in the rate of pertussis immunization in this country could result in a major epidemic with unnecessary deaths and neurological disorders.[86]

Despite general agreement that a safer yet equally effective vaccine is desirable, there is considerable controversy about the current availability

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83. S. Rep. No. 393, 98th Cong., 2d Sess. 14, *reprinted in* 1984 U.S. Code Cong. & Admin. News 4804, 4817.

84. *See* Peter, *supra* note 3, at 981.

85. *See* H. Coulter & B. Fisher, DPT: A Shot in the Dark (1985). The authors are members of Dissatisfied Parents Together, which proposes that parents receive written notice of the risks and benefits of pertussis vaccine and that health care providers record the manufacturer and lot number of every dose administered. The parents also advocate mandatory reporting of severe reactions. *See also* Reitze, *supra* note 8, at 197-99.

86. Peter, *supra* note 3, at 982.

of a better alternative. Opponents of whole-cell pertussis vaccine claim that either an extracted or an acellular vaccine is as effective and safer than the whole-cell variety and should be approved and marketed in the United States. The manufacturers and federal agencies claim that neither type has been proven sufficiently reliable to be licensed at this time.[87]

In 1962, Eli Lilly and Company began to market Tri-Solgen, an extract made from part of the *Bordetella pertussis* bacterium.[88] This split-cell vaccine passed the same laboratory tests for toxicity and potency as the whole-cell vaccine but differed from the latter in its solubility. It was considered effective with a lower incidence of systemic and local reactions than the whole-cell vaccine, but clinical trials were never conducted to determine its true efficacy, potency and safety.[89] In 1976, Lilly ceased manufacture of Tri-Solgen because it was not profitable.[90]

Wyeth Laboratories took an option from Lilly on the manufacturing technology but could not obtain Lilly's license for the product because federal licensing is dependent on the manufacturing facility as well as the manufacturing process. Vaccines by different manufacturers with the same design and purpose are licensed as separate products.[91] Wyeth developed its own extracted vaccine in the late 1970's, but the FDA rejected its license application in 1982 on the basis of possible toxicity and insufficient clinical evidence that it was better than whole-cell pertussis vaccine.[92] Clinical trials are expensive and difficult to conduct in a population which already has achieved a ninety percent immunization rate.[93] Consequently, Wyeth's application has remained inactive since

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87. U.S. Brief, *supra* note 32, at 10.

88. *Id.*

89. David, *supra* note 33, at 374-75.

90. Reitze, *supra* note 8, at 196.

91. U.S. Brief, *supra* note 32, at 11. *See also* 21 C.F.R. § 312 (1988).

92. The results of two small clinical trials indicated fewer mild reactions to Wyeth's new vaccine than the whole-cell type, but there were two serious reactions in the test group. Using new and different potency tests, the FDA also found Wyeth's vaccine to be less potent than Tri-Solgen. U.S. Brief, *supra* note 32, at 11-12. The criteria for federal licensing of vaccines are much more stringent now than in the 1960's and require substantial evidence of successful clinical trials. *National Childhood Vaccine-Injury Compensation Act; Hearing Before the Senate Comm. on Labor and Human Resources*, 98th Cong., 2d Sess. 140 (1984) (letter from Walter Dowdle, director, Center for Infectious Diseases, and chairman, Inter-agency Group to Monitor Vaccine Development, Production and Usage, to Jeffrey Schwartz, president, Dissatisfied Parents Together, Aug. 4, 1983). *See also Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review*, 50 Fed. Reg. 51,002 (1985) [hereinafter *Biologics Review*]. This 115-page publication contains a comprehensive statement of the Panel on Review of Bacterial Vaccines and Toxoids and the FDA's response. The FDA did not find sufficient basis to assume that split-cell pertussis vaccine is any more or less safe than the whole-cell vaccine. *Id.* at 51,051-52.

93. Peter, *supra* note 3, at 981.

1982. In 1985, the FDA revoked Lilly's license for Tri-Solgen at Lilly's request.[94]

Acellular vaccines contain antigens rather than cells of the *Bordetella pertussis* organism. They appear to be less toxic than the whole-cell variety, but there is considerable debate as to whether they are as effective as either the split-cell or whole-cell vaccines. Acellular vaccines have been used for mass immunization in Japan since 1981 with encouraging results,[95] but their true impact on the incidence of pertussis is not clear from Japanese usage. Pertussis had reached epidemic proportions in the late 1970's as the acceptance rate of the whole-cell vaccine declined.[96] The Japanese government approved six acellular vaccines composed of different antigens in different ratios and put them into widespread use without conducting controlled studies to determine the safety and efficacy of each vaccine.[97] The Japanese experience is encouraging but does not provide the clinical evidence required for licensing in the United States.

As vaccine litigation mounts, extensive public and private research continues toward the development of a safer alternative. Vaccine manufacturers have invested substantial sums in research on acellular vaccines.[98] The National Institute of Allergy and Infectious Diseases (NIAID) and other federal agencies support the development of a safer pertussis vaccine,[99] and the 1986 Vaccine Act established a new program for vaccine research.[100]

The major obstacle in all these efforts has been the lack of adequate clinical evidence to support the safety and efficacy of new vaccines. Large-scale clinical trials are impractical in the United States, where the incidence rate of pertussis is so low that a prohibitively large group would have to be studied. An unvaccinated control group would be difficult to find because vaccination is compulsory in most states. In

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94. U.S. Brief, *supra* note 32, at 12.

95. Bernier, *Current Status of New Pertussis Vaccine Studies, reprinted in* PROCEEDINGS OF THE 20TH IMMUNIZATION CONFERENCE, CENTERS FOR DISEASE CONTROL 41 (1985). Dr. Bernier was Chief, Epidemiologic Research Section, Division of Immunization, Center for Prevention Services, Centers for Disease Control.

96. *See* Kanai, *supra* note 61, at 112-14.

97. U.S. Brief, *supra* note 32, at 14-15. Field studies in Tokyo involving 5,000 children indicated that acellular vaccines appeared to be as effective as the whole-cell vaccine with fewer side effects. *See* David, *supra* note 33, at 375. The Japanese studies have been criticized, however, for relying on individuals to report adverse reactions to public health authorities; passive reporting systems are not a reliable indicator of the true incidence of serious reactions. U.S. Brief, *supra* note 32, at 15.

98. *Childhood Immunizations*, *supra* note 49, at 38. The cost of developing an improved acellular pertussis vaccine has been estimated at $20 million. *Id.*

99. S. REP. No. 483, 99th Cong., 2d Sess. 6 (1986). *See also Biologics Review*, *supra* note 92, at 51,112.

100. 42 U.S.C. §§ 300aa-1 to 300aa-6 (Supp. IV 1986).

addition, the use of an unvaccinated control group could create an ethical problem because an effective and relatively safe vaccine already exists.[101] If acellular vaccines are to be licensed in the United States, the clinical evidence must be produced elsewhere.

Scientists are watching one study presently underway in Sweden, where the incidence of pertussis increased significantly after use of the whole-cell vaccine was discontinued in the mid 1970's. Swedish public health officials consulted with American scientists to design the present clinical trial, which began in 1986 and is primarily funded by the United States Department of Health and Human Services.[102] Sweden was selected because the incidence of pertussis is high, immunization is neither recommended nor required, and the country's medical care system is sufficiently advanced to conduct the study properly.[103] Data concerning adverse reactions is being evaluated, but the results must be verified in more comprehensive studies before the FDA's strict licensing standards are satisfied.

At the present time, federal public health experts are not convinced that alternative pertussis vaccines are safe and effective.[104] Whole-cell pertussis vaccine thus remains the only FDA-approved product available to carry out federal immunization policies. The majority of states require vaccination with whole-cell pertussis vaccine but allow those who suffer vaccine-related injuries to bring suit against the manufacturer for damages. Tort judgments against a manufacturer who is prohibited from marketing a different product may induce the manufacturer to withdraw his product from the market altogether because that product has been rendered unprofitable. Whether pertussis vaccine remains available depends primarily upon the impact of vaccine-damage lawsuits on manufacturers' ability and willingness to continue production and upon the feasibility of alternative forms of compensation for vaccine victims.

II. The Crisis in Vaccine Injury Litigation

Traditionally, compensation for vaccine-related injuries has been available through the tort system. A medical malpractice claim against

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101. Bernier, *Prospects for a New Pertussis Vaccine*, *reprinted in* Proceedings of the 17th Immunization Conference, Centers for Disease Control 78 (1982). *See also Childhood Immunizations*, *supra* note 49, at 38.

102. U.S. Brief, *supra* note 32, at 14. Two of the Japanese acellular vaccines were studied. A total of 3,800 infants between six and nine months of age received two doses of either a placebo or one of the vaccines. Although preliminary information indicated that the trial would provide proof of the effectiveness of acellular vaccines, the safety of these vaccines remains in doubt because four children died within five months after the final injection. All four deaths involved severe bacterial infections, but their relationship to the vaccines was unclear. In addition, this study may have been too small to yield conclusive evidence of the rate of adverse reactions. *Id.* at 13-15.

103. *Id.* at 13.

104. *Id.* at 16.

the health care provider requires proof of inadequate medical care.[105] Unless the health care provider has ignored previous reactions or other known contraindications, there is usually little evidence to support a malpractice claim.[106] The alternative is to bring suit against the manufacturer on a products liability theory.

DPT litigation mushroomed in the early 1980's following widespread publicity about vaccine-related injuries.[107] The president of Lederle Laboratories, testifying before a Senate committee in 1985, stated that all but two of the over ninety DPT cases filed against Lederle in more than forty years of distributing the vaccine had been filed since 1982.[108] The total dollar demand of DPT lawsuits against Lederle was two hundred times greater than its total sales of DPT vaccine in 1983.[109] Throughout the industry, plaintiffs sought an estimated $1.5 billion in damages for vaccine-related injuries in 1985.[110]

At first, many of these cases were settled because large corporations do not fare well before juries when the complainant is a brain-damaged child.[111] As the number and size of claims skyrocketed, settlement became less feasible and the price of DPT vaccine increased dramatically to offset the manufacturers' mounting litigation expenses.[112] Some producers simply left the market altogether, citing increased exposure to liability and the resulting difficulty in obtaining adequate liability insurance.[113] In 1963, eight drug companies manufactured DPT vaccine.[114] By 1986, Lederle was the only American company which manufactured and dis-

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105. Reitze, *supra* note 8, at 192-93. *See also* Preiser, *supra* note 48, at 12-13. The physician has a duty to inquire about the potential vaccinee's medical history, to warn parents of possible adverse reactions, and to instruct parents to watch for and report symptoms of possible reactions. *Id.*

106. *See* Davis v. Wyeth Laboratories, 399 F.2d 121 (9th Cir. 1968). When prescription drugs are accompanied by warnings to the physician, "the choice involved is essentially a medical one involving an assessment of medical risks in the light of the physician's knowledge of his patient's needs and susceptibilities." *Id.* at 130.

107. *See supra* text accompanying notes 84-85.

108. *National Childhood Vaccine Injury Compensation Act of 1985: Hearings Before the Senate Comm. on Labor and Human Resources*, 99th Cong., 1st Sess. 245 (1985) (statement of Robert Johnson, president, Lederle Laboratories).

109. *1984 Vaccine Hearings*, *supra* note 55, at 229 (statement of Robert Johnson, president, Lederle Laboratories).

110. Reitze, *supra* note 8, at 194.

111. *Id.*

112. A 1987 Lederle invoice to a private physician reflected a unit price of $55.00 per vial of DPT vaccine with a liability surcharge of $78.75. Copy on file at the office of the *Indiana Law Review.*

113. H.R. REP. No. 908, 99th Cong., 2d Sess. 6, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS 6344, 6347-48.

114. Reitze, *supra* note 8, at 194.

tributed its own vaccine.[115] The impact of this crisis on future supplies of DPT vaccine is ominous.

In 1987, a jury awarded $15 million to a brain-damaged child who had been injured by DPT vaccine.[116] The jury found that the manufacturer, Wyeth Laboratories, was negligent and further that its DPT vaccine was unreasonably dangerous due to defective design and inadequate warnings. The thrust of the plaintiff's claim was that Wyeth had the technical ability to produce a safer and more effective vaccine but had refused to spend money on the research and development necessary to obtain FDA approval of an alternate formula. As noted earlier, new vaccines will not be licensed without substantial proof of their safety and efficacy.[117] Because large-scale clinical studies are not only expensive but impractical to conduct in the United States,[118] the few remaining manufacturers may be reluctant to pursue the development of new vaccines and risk further exposure to liability. With no assurance that future juries will deem their efforts adequate, it may be economically unwise to undertake such financial risks. The better choice may be to join the exodus from the vaccine market. Congressional concern for the instability of the market led to passage of the 1986 Vaccine Act.[119] It became apparent that the federal government might have to bear the entire burden of research, production and distribution at substantial taxpayer expense if the manufacture of DPT vaccine became too costly for private interests.

Although the Vaccine Act provided a legislative alternative in the form of optional no-fault compensation, the Act did not resolve the liability dilemma because it did not preclude the opportunity to recover in tort.[120] Consequently, courts will continue to encounter the tension

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115. *Id.* Lederle also distributes vaccine manufactured by Wyeth Laboratories under the Lederle label. In 1984, Wyeth ceased distribution due to the uncertainty and cost of litigation and entered an agreement to sell its vaccine to Lederle, which at that time purchased Wyeth's DPT vaccine for twenty cents a dose, distributed it for $2.80 a dose, and assumed all litigation costs on Wyeth's behalf. *1984 Vaccine Hearings*, *supra* note 55, at 295 (statement of Daniel Shaw, M.D., vice-president, Wyeth Laboratories).

A Canadian company, Connaught Laboratories, distributes a more expensive vaccine in the United States. Two states, Massachusetts and Michigan, make their own. *See* Reitze, *supra* note 8, at 194.

116. Graham v. Wyeth Laboratories, No. 85-1481-R (D. Kan. Oct. 4, 1987).

117. *See supra* notes 92-93 and accompanying text.

118. *See supra* text accompanying notes 101-04.

119. H.R. Rep. 908, 99th Cong., 2d Sess. 7, *reprinted in* 1986 U.S. Code Cong. & Admin. News 6344, 6348.

120. Congress could have made no-fault compensation the exclusive remedy for vaccine-related injuries, but it chose to retain tort law as a secondary means of redress. Some writers believe that this structure may indicate a policy decision to sacrifice some

between tort awards and the federal government's policy of nationwide immunization. Despite the national significance of this problem, it has been dealt with in a piecemeal fashion under theories of products liability law which vary from one jurisdiction to another. The uncertainties and inconsistent results produced by the tort system reveal a need not only for an alternate source of compensation, but for a better definition of the function of the tort system itself in vaccine injury cases.

Vaccine litigation exemplifies many of the problems of products liability law.[121] Products liability encompasses three distinct causes of action: warranty, negligence and strict liability. Most DPT cases involve claims on all three grounds, but various jurisdictions apply different legal theories to similar facts with inconsistent results.[122] Liability insurers,

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degree of predictability in vaccine litigation in order to provide manufacturers with an incentive to produce safe vaccines. *See* Schwartz & Mahshigian, *National Childhood Vaccine Injury Act of 1986: An Ad Hoc Remedy or a Window for the Future*, 48 Ohio St. L.J. 388, 395 (1987). Furthermore, the federal compensation programs may be terminated, leaving tort law the sole recourse for vaccine injuries. *See supra* text accompanying notes 17-18.

121. Five parameters of uncertainty have been identified in products liability law: (1) multiple causes of action; (2) divergent definitions of "defect;" (3) judicial creation and extension of theories of recovery; (4) differences in defenses allowed in strict liability actions; and (5) variations in the admissability of subsequent repairs evidence. Reed & Watkins, *supra* note 6, at 396. For an analysis of the various legal theories involved in DPT litigation, see Burke, *supra* note 6.

122. Ordinarily, the manufacturer will move for partial summary judgment to have one or more of the claims dismissed before trial. A survey of six federal district court decisions, applying the law of six different states to similar facts, illustrates the inconsistencies in DPT vaccine litigation.

Breach of express warranty: defendant's motion was granted in one case and denied in another.

Breach of implied warranty of merchantability: defendant's motion was granted in one case and denied in five (two courts stated that this claim was either the same as or superseded by strict liability theories).

Breach of implied warranty of fitness for a particular purpose: defendant's motion was granted in two cases and denied in two.

Negligent design, manufacture and/or warning: defendant's motion was denied in four cases; in the other two, defendant's motion was granted with regard to the negligent warning claim but denied with regard to the negligent design claim.

Strict liability for manufacturing defect: defendant's motion was granted in three cases and denied in one.

Strict liability for design defect: defendant's motion was granted in two cases and denied in four.

Strict liability for inadequate warning: defendant's motion was granted in four cases and denied in one.

See Jones v. Lederle Laboratories, 695 F. Supp. 700 (E.D.N.Y. 1988); Morris v. Parke Davis & Co., 667 F. Supp. 1332 (C.D. Cal 1987); Martinkovic v. Wyeth Laboratories, Inc., 669 F. Supp. 212 (N.D. Ill. 1987); Graham v. Wyeth Laboratories, 666 F. Supp. 1483 (D. Kan. 1987); Foyle v. Lederle Laboratories, 674 F. Supp. 530 (E.D.N.C. 1987); Smith v. Wyeth Laboratories, Inc., Civ. No. 84-2002, mem. (S.D.W. Va. Aug. 21, 1986).

confronted with these inconsistencies and unable to evaluate risks with reasonable certainty, consequently tend to rely on a worst-possible-case basis to predict future exposure to liability.[123]

A. Breach of Warranty

In a claim for breach of warranty, the focus is on the condition of the product. The plaintiff must show that the manufacturer made either express or implied representations about the product which it failed to meet. The language in a package insert contains such representations, or affirmations of fact, upon which a user reasonably may rely even though the manufacturer may be unaware of the falsity of the representations.[124] A warranty that a product is reasonably fit for the purpose intended also may be implied in a merchant's contract for sale without oral or written representations.[125] If the product fails to perform as warranted, it is deemed defective, and the manufacturer may be held liable.[126] Under a warranty claim, a vaccine may be defective if it contains impurities or foreign ingredients which render it inherently dangerous.[127] The plaintiff must show that the defect proximately caused his injuries and that he relied on the manufacturer's representations. Reliance by the purchasing physician is usually sufficient in a suit brought by a vaccinee against the manufacturer.[128]

Warranty theories are subject to limitations which create difficulties for plaintiffs in vaccine damage suits. Vaccine manufacturers cannot guarantee that no child will suffer a reaction and, therefore, may attempt to avoid liability for breach of warranty by placing express disclaimers in the package inserts.[129] In addition, courts are reluctant to extend

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123. Reed & Watkins, *supra* note 6, at 448. *See infra* note 142.

124. Grinnel v. Charles Pfizer & Co., 274 Cal. App. 2d 424, ____, 79 Cal. Rptr. 369, 378-79 (1969) (manufacturer liable for misrepresentation in package insert stating that there were no known contraindications to oral polio vaccine because manufacturer should have known that the recommendations of the Surgeon General's Advisory Committee on Poliomyelitis Control had been updated).

125. L. Frumer & M. Friedman, Products Liability § 3.02[2] (1987). *See also* U.C.C. §§ 2-314, 2-315 (1978).

126. L. Frumer & M. Friedman, *supra* note 125, at § 3.01[1][a].

127. Chambers v. G.D. Searle & Co., 441 F. Supp. 377, 380 (D. Md. 1975) (evidence was insufficient to permit recovery on theories of fraud, implied warranty, or negligence for stroke suffered after plaintiff took oral contraceptive), *aff'd*, 567 F.2d 269 (4th Cir. 1977).

128. Toole v. Richardson-Merrell, Inc., 251 Cal. App. 2d 689, ____, 60 Cal. Rptr. 398, 411 (1967) (drug manufacturer's statements about drug's safety were misrepresentations of material fact upon which plaintiff's physician relied).

129. *See* W. Keeton, D. Dobbs, R. Keeton & D. Owen, Prosser and Keeton on Torts 691 (5th ed. 1984). A manufacturer's disclaimer "means that he is free to insert in his contract of sale an effective agreement that he does not warrant at all, or that he warrants only against certain consequences or defects." *Id.* The courts generally do not favor disclaimers of consumer goods. *Id.* at 692. *See also* U.C.C. §§ 2-316, 2-719 (1978).

recovery under a breach of warranty theory to unusually susceptible plaintiffs unless the product would be unfit for ordinary use.[130] Other problems with warranty claims arise in those jurisdictions which bar such claims for lack of privity between the ultimate consumer and the manufacturer or for the victim's failure to give the seller notice of the breach within a reasonable period of time.[131] Due to the various problems of contractual warranty theories in this type of litigation, DPT plaintiffs prefer to base their claims on tort theories.[132]

B. Negligence

Under a negligence theory, the DPT plaintiff must prove that he was exposed to an unreasonable risk of harm by the manufacturer's failure to use due care. The focus is on the conduct of the manufacturer in making and distributing a harmful product. A negligence claim may be successful if the vaccine is contaminated in the production process and thus fails to meet either federal or the manufacturer's own standards.[133] Proof of negligence is difficult to obtain, however, when the entire production process is peculiarly within the manufacturer's control.[134]

The FDA has determined that the risk of harm is reasonable if the manufacturer complies with all federal regulatory standards,[135] but courts often do not agree. Some have found that federal regulation establishes only minimum standards and manufacturers should be held to a higher standard of care.[136]

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130. *Chambers*, 441 F. Supp. at 380. *See also* Whittington v. Eli Lilly & Co., 333 F. Supp. 98 (S.D.W. Va. 1971) (recovery denied to plaintiff who became pregnant after taking oral contraceptive on ground that seller is not liable for breach of warranty to unusually susceptible buyer).

131. David, *supra* note 33, at 379.

132. *Id.*

133. *See, e.g.*, Knox v. Eli Lilly & Co., 592 F.2d 317 (6th Cir. 1979) (suit by teenager who developed poliomyelitis as an infant shortly after receiving allegedly contaminated polio vaccine); Griffin v. United States, 351 F. Supp. 10 (E.D. Pa. 1972), *aff'd in part, rev'd in part*, 500 F.2d 1059 (3d Cir. 1974) (release of polio vaccine that did not conform to federal regulatory standards was negligence *per se*).

134. D. Noel & J. Phillips, Products Liability 30 (2d ed. 1981). *See also* Wack v. Lederle Laboratories, 666 F. Supp. 123 (N.D. Ohio 1987) (no preemption of design defect, inadequate warning, and punitive damages claims for DPT vaccine injury). Claims based on negligence in the manufacturing process or manufacturing defect are nearly impossible to prove because a vaccine is consumed and not available for analysis. *Id.* at 128.

135. *See supra* text accompanying note 65 and *infra* text accompanying note 200.

136. *See, e.g.*, Martinkovic v. Wyeth Laboratories, Inc., 669 F. Supp. 212, 217 (N.D. Ill. 1987) ("compliance is but one factor for the jury to consider in deciding the reasonableness of the manufacturer's conduct"); Mahr v. G. D. Searle & Co., 72 Ill. App. 3d 540, 561, 390 N.E.2d 1214, 1229 (1979) (compliance with FDA regulations is minimal and does not change duties arising under common law).

In *Toner v. Lederle Laboratories*,[137] a jury rejected breach of warranty and strict liability claims but found the manufacturer negligent in failing to develop and market an alternative vaccine that would have been safer. The $1.13 million judgment was upheld despite Lederle's argument that it could not have marketed a safer vaccine under existing FDA regulations.[138] This rationale may represent an inappropriate judicial intrusion into an area of federal policy-making which has been delegated to the FDA. In *Abbot v. American Cyanamid Co.*,[139] for example, a district court acknowledged that the FDA has sole authority to regulate the safety and design of drugs and that is was not a proper question for the courts. The Fourth Circuit Court of Appeals disagreed, however, and reversed the district court's grant of summary judgment in favor of the manufacturer.[140] The court of appeals discerned from the 1986 Vaccine Act and the 1987 Vaccine Amendments a congressional policy that state law should "[strike] the balance between safety and quantity."[141]

These results leave manufacturers with little choice. Until the FDA decides that other types of DPT vaccine are sufficiently safe to meet licensing requirements, manufacturers will either avoid future liability by ceasing production of the only approved vaccine or continue to raise the price to keep up with insurance and litigation costs. Ultimately, consumers in jurisdictions which limit manufacturers' liability may be forced to pay for remedies available only in more liberal jurisdictions.[142]

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137. 779 F.2d 1429 (9th Cir. 1986).

138. The Ninth Circuit Court of Appeals certified four questions of law to the Idaho Supreme Court: (1) do Restatement (Second) of Torts § 402A and comment k apply to strict liability and negligence claims under Idaho law; (2) was there evidence from which a jury could find that the vaccine was unavoidably unsafe; (3) could the jury find the defendant negligent for failure to develop an alternate vaccine; and (4) were the jury instructions on the issue of negligence proper. *Id.* at 1433. The Idaho court adopted § 402A and comment k, holding that DPT vaccine is an unavoidably unsafe product exempt from strict liability when accompanied by proper warnings, but refused to shield the manufacturer from negligence claims for failure to develop a safer alternative. Toner v. Lederle Laboratories, 112 Idaho 328, 732 P.2d 297 (1987). On remand, the court of appeals affirmed the jury's findings as consistent under state law. Toner v. Lederle Laboratories, 828 F.2d 510 (9th Cir. 1987). *See* RESTATEMENT (SECOND) OF TORTS § 402A and comment k (1965); *see also infra* notes 144 & 153.

139. Civ. No. 86-857-A, mem. at 5 (E.D. Va. Mar. 9, 1987), *rev'd*, 844 F.2d 1108 (4th Cir. 1988).

140. 844 F.2d 1108 (4th Cir. 1988).

141. *Id.* at 1113.

142. *See* Reed & Watkins, *supra* note 6, at 428. The authors note: "Since products are marketed on a national basis and rates are set on the basis of national experience, the influence of the so-called 'worst-case' is limited not to the most extreme case within one jurisdiction, but to the most extreme case in any jurisdiction." *Id.*

C. Strict Liability

The plaintiff has fewer proof problems with a strict liability claim because the manufacturer's conduct and representations are irrelevant. In one of the first judicial pronouncements of modern strict products liability, Justice Traynor explained that the manufacturer is "strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being."[143] In 1965, the American Law Institute embodied this standard in Section 402A of the Restatement (Second) of Torts.[144]

Section 402A has been widely adopted,[145] but courts give varying interpretations to the Restatement's terminology. Under section 402A, products in a "defective condition unreasonably dangerous" are subject to strict liability. One view interprets this phrase to mean dangerously defective, another defines it as not reasonably safe, and yet another finds that the terms "defective" and "unreasonably dangerous" are synonymous.[146] Some courts reject the "unreasonably dangerous" part of the formula altogether as a negligence standard which does not belong in a theory of strict liability,[147] while others equate the formula to negligence *per se*.[148]

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143. Greenman v. Yuba Power Prods., 59 Cal. 2d 57, 60, 377 P.2d 897, 900, 27 Cal. Rptr. 697, 700 (1962).

144. The *Restatement (Second) of Torts* § 402A (1965) states as follows:

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
  (a) the seller is engaged in the business of selling such a product, and
  (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although
  (a) the seller has exercised all possible care in the preparation and sale of his product, and
  (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

145. J. Phillips, Products Liability 50 (3d ed. 1988). However, section 402A has not been adopted universally. For example, in Foyle v. Lederle Laboratories, 674 F. Supp. 530 (E.D.N.C. 1987), the court rejected plaintiff's strict liability claims for DPT injury because North Carolina law does not provide for strict liability actions in products liability cases. *Id.* at 535. The court noted that "[t]here is no provision in North Carolina that tracks the language of the Restatement of Torts § 402A as there is in other states." *Id.*

146. Reed & Watkins, *supra* note 6, at 400.

147. *See* Barker v. Lull Eng'g Co., 20 Cal. 3d 413, 573 P.2d 443, 143 Cal. Rptr. 225 (1978); Cronin v. J. B. E. Olson Corp., 8 Cal. 3d 121, 501 P.2d 1153, 104 Cal. Rptr. 433 (1972).

148. *See* Dippel v. Sciano, 37 Wis. 2d 443, 155 N.W.2d 55 (1967).

The question is ultimately one of degree in the case of products like vaccine because absolute safety often is not technologically feasible. Jurisprudence has developed two theoretical models of defectiveness to aid in determining whether a product is sufficiently safe or unreasonably dangerous: consumer expectations and risk-benefit analysis. Under the consumer expectations approach, a product contains an unreasonably dangerous defect if it does not meet the reasonable expectations of the ordinary consumer.[149] The risk-benefit approach balances the probability and seriousness of harm against the costs and feasibility of precautionary measures.[150] A product is not defective if its social utility and the cost of improving its safety outweigh the accident costs associated with the product.[151]

The usefulness of each model depends in part on the nature of the product and the context of the claim. In vaccine cases, the ordinary consumer expects to achieve immunity from disease through vaccination. He does not expect to suffer severe side-effects. A DPT manufacturer, however, cannot always meet the consumer's expectations no matter how much care goes into the manufacturing process.[152] The risk-benefit model,

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149. *See, e.g.*, Bemis Co. v. Rubush, 427 N.E.2d 1058 (Ind. 1981); Vincer v. Esther Williams All-Aluminum Swimming Pool Co., 69 Wis. 2d 326, 230 N.W.2d 794 (1975). *See also* RESTATEMENT (SECOND) OF TORTS § 402A comment i (1965). The drafters of the Restatement explained that "[t]he article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." *Id.*

150. Dean Wade proposed the following factors for consideration in a risk-benefit analysis:

> (1) The usefulness and desirability of the product—its utility to the user and to the public as a whole.
>
> (2) The safety aspects of the product—the likelihood that it will cause injury, and the probable seriousness of the injury.
>
> (3) The availability of a substitute product which would meet the same need and not be unsafe.
>
> (4) The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.
>
> (5) The user's ability to avoid danger by the exercise of care in the use of the product.
>
> (6) The user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions.
>
> (7) The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.

Wade, *On the Nature of Strict Tort Liability for Products*, 44 MISS. L.J. 825, 837-38 (1973).

151. *See, e.g.*, Cepeda v. Cumberland Eng'g Co., 76 N.J. 152, 386 A.2d 816 (1978); Phillips v. Kimwood Mach. Co., 269 Or. 485, 525 P.2d 1033 (1974).

152. The consumer expectations model of design defect has been criticized as un-

therefore, provides a more appropriate basis for evaluating the defectiveness of vaccine products, particularly with respect to claims of defective design. The ultimate question must be whether a vaccine's social utility is outweighed by its accident costs.

The drafters of the Restatement applied a risk-benefit analysis to define unavoidably unsafe products in comment k of Section 402A.[153] Although the FDA has adopted the medical community's opinion that the benefits of DPT vaccine outweigh its risks, many courts disagree that vaccines should be exempt from strict liability under comment k. A vaccine deemed crucial to the national policy of immunization would seem to qualify under the first part of the comment k test as a socially useful and desirable product despite known risks. The difficulty lies in the second part of the test which requires that such products be accompanied by proper directions and warnings.

The standard generally used in warning cases resembles the negligence standard: the manufacturer must know or have reason to know of the danger of his product.[154] The issue then becomes "whether the manu-

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workable and inappropriate for products such as drugs which serve society well but produce harmful side effects. *See* Keeton, *Products Liability—Design Hazards and the Meaning of Defect*, 10 CUMB. L. REV. 293, 303 (1979).

153. The *Restatement (Second) of Torts* § 402A comment k (1965) (emphasis in original) states as follows:

> *Unavoidably Unsafe Products*. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

154. W. KEETON, D. DOBBS, R. KEETON, & D. OWEN, PROSSER AND KEETON ON TORTS 697 (5th ed. 1984). *See also* RESTATEMENT (SECOND) OF TORTS § 402A comment j

facturer, with such knowledge, has distributed an unreasonably dangerous product. In light of comment k of section 402A, the unreasonable dangerousness of this unavoidably unsafe product turns on whether the warning given with the product adequately apprises the recipient of those dangers."[155]

Traditionally, the "learned intermediary" rule has limited the manufacturer's duty to warn to physicians who must weigh the risks and benefits for each patient.[156] The growing popularity of public health clinics, where the cost of vaccination is lower, has created a situation in which this rule does not necessarily apply. There may not be one administering physician who can give such individual attention to each patient. Consequently, some jurisdictions extend the manufacturer's duty to ensure that proper warnings actually reach vaccine recipients.[157]

This duty imposes a difficult burden on the manufacturer who has no direct contact with the ultimate consumer. Vaccine purchasers could be required to sign a contract promising to read the manufacturer's warnings to vaccinees (or their parents) and obtain their consent before immunization.[158] This solution may be appropriate when the purchaser is a private physician or a clinic, but it becomes less feasible as the relationship between the manufacturer and user becomes more remote. The federal government purchases and distributes vast amounts of DPT vaccine to state health departments, which in turn distribute the vaccine to local clinics. The manufacturer has more control at the beginning of the chain, but the obligation should be imposed at the end with the party who administers the vaccine.

Controversy also abounds over the adequacy of the warnings given. DPT manufacturers list all known risks and contraindications in package

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(1965). There is, however, some authority for the proposition that the negligence standard is irrelevant in failure to warn cases premised upon theories of strict liability. *See, e.g.*, Nesselrode v. Executive Beechcraft, Inc., 707 S.W.2d 371, 383 & n.12 (Mo. 1986).

155. Petty v. United States, 740 F.2d 1428, 1441 (8th Cir. 1984) (manufacturer and the government are strictly liable for failure to adequately warn of risk of serum sickness associated with swine flu vaccine).

156. Martinkovic v. Wyeth Laboratories, Inc., 669 F. Supp. 212, 215 (N.D. Ill. 1987) (citing Kirk v. Michael Reese Hosp. & Medical Center, 117 Ill. 2d 507, 513 N.E.2d 387 (1987) (drug manufacturer's duty extends only to physician, who in turn uses his medical judgment to relay warnings to his patient)).

157. Givens v. Lederle Laboratories, 556 F.2d 1341 (5th Cir. 1977); Reyes v. Wyeth Laboratories, 498 F.2d 1264 (5th Cir. 1974), *cert. denied*, 419 U.S. 1096 (1974); Davis v. Wyeth Laboratories, 399 F.2d 121 (9th Cir. 1968).

158. David, *supra* note 33, at 391. Other options include oral warnings, posters, or other announcements advertising the manufacturer's warnings, but the sufficiency of these methods is unclear. Davis v. Wyeth Laboratories, 399 F.2d at 131. *See also* Note, *Mass Immunization Cases: Drug Manufacturers' Liability for Failure to Warn*, 29 VAND. L. REV. 235, 254 (1976).

inserts in compliance with FDA requirements,[159] but a court may find that FDA review is merely a matter of form rather than approval of the substantive content of the warning.[160] In some jurisdictions, compliance with federal warning regulations is merely a factor for the jury to consider[161] in the same way that FDA regulation of the manufacturing process provides only a minimal standard rather than a reasonable standard of care in negligence claims.

In addition, warnings which fully comply with FDA standards have been found inadequate for failing to impress upon the administering physician the need for caution. In *Givens v. Lederle Laboratories*,[162] the physician testified that the statement of risks in a package insert for oral polio vaccine—one in three million—was so nebulous that he found no need to warn his patient.[163] The manufacturer, not the physician, was liable for failure to warn.

DPT manufacturers also must use vague terms concerning the risk rate because there is no reliable scientific data on which to base an accurate estimate. In *Martinkovic v. Wyeth Laboratories, Inc.*,[164] the court cited four scientific studies which placed the risk of convulsions after DPT vaccinations between one in 300 and one in 800,000.[165] Wyeth's package insert identified the possible reactions and noted that the incidence was unknown but seemed to be exceedingly rare. The court denied summary judgment on the warning issue and left it to the jury to decide which study to believe and whether the rate could be categorized as "exceedingly rare."[166]

A different result was reached in *Conafay v. Wyeth Laboratories*.[167] The plaintiff's warning claim was dismissed because Wyeth's warning in a similar package insert was held to be sufficient to alert the physician

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159. 21 C.F.R. §§ 601.12, 601.25 (1988).

160. Fraley v. American Cyanamid, 570 F. Supp. 497, 505 (D.C. Colo. 1983).

161. *See, e.g.*, Martinkovic v. Wyeth Laboratories, Inc., 669 F. Supp. 212, 217 (N.D. Ill. 1987).

162. 556 F.2d 1341 (5th Cir. 1977).

163. *Id.* at 1345.

164. 669 F. Supp. 212 (N.D. Ill. 1987).

165. *Id.* at 216 (citing studies which place the rate of convulsions at one in 300 children, one in 1,750, one in 7,000, and one in 800,000).

166. *Id.* The warning accompanied Wyeth's 1982 vaccine. *Id.* at 215. In 1984, the language of the package insert was revised and adopted by both Wyeth Laboratories and Lederle Laboratories. It now states: "These reactions have been reported to occur rarely following the injection of this product and they may be fatal or result in permanent damage to the central nervous system. Pertussis vaccine has been associated with a greater proportion of adverse reactions than many other childhood immunizations." Copy of package insert on file at the office of the *Indiana Law Review*.

167. Civ. No. 83-00637 (D.D.C. 1985). On appeal, the case was remanded due to a procedural error. Conafay v. Wyeth Laboratories, 793 F.2d 350 (D.C. Cir. 1986).

to the risks of DPT vaccine, and the manufacturer's duty to warn was discharged when the physician prescribed the vaccine after considering the warning.

The public has a right to the best possible warning, but manufacturers are beset with uncertainty in deciding upon which information they should rely and what data to include. They may be liable for understating the risks, especially in those jurisdictions which require that the risks be precisely communicated to the physician or to the vaccinee. Manufacturers cannot simply withdraw their products from those jurisdictions to avoid liability because they do not always control distribution, especially with the federal government as a major purchaser. Overemphasizing the risks, however, may cause undue concern and deter participation in immunization programs.[168]

Furthermore, the adequacy of the warning which reaches the vaccinee may be irrelevant in jurisdictions where immunization is mandatory. Although medical exemptions are universally recognized, only twenty-two states allow parents to refuse vaccination for philosophical reasons.[169] In the other twenty-eight states, parents would be precluded from making an informed choice even if they were fully apprised of the risks.

A common justification for imposing strict liability is the theory of risk allocation, which proposes that manufacturers can bear the risk of injury caused by defective products better than consumers. When inevitable injuries are statistically foreseeable, manufacturers can insure against such foreseeable risks and factor them into the cost of the product.[170] The theory of risk allocation is not appropriate in vaccine litigation, however, because the risks are unpredictable and reliable statistics are lacking. Insurance is expensive if available at all because it is based on a worst-case scenario, and DPT manufacturers have been unable to bear the losses or spread the risks of their product as well as manufacturers of other types of products.

Tort remedies for vaccine victims have created an untenable situation which casts a cloud of uncertainty over the future of mass immunization. If the cost of DPT vaccine continues to skyrocket until it becomes too high for consumers to pay, the policy of widespread immunization will be undermined and the potential for epidemics of pertussis will increase. The tort system is designed to compensate victims, but society may suffer greater harm if DPT vaccine becomes too costly or if manufacturers are forced out of the market by inconsistent standards of liability and excessive judgments.

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168. Petty v. United States, 740 F.2d 1428, 1441-42 (8th Cir. 1984) (Bright, J., dissenting).

169. Centers for Disease Control, State Immunization Requirements (1986).

170. David, *supra* note 33, at 398.

Consequently, manufacturers have asked the courts to decide whether claims for vaccine injury are proper matters for adjudication at all. They argue that congressional intent to displace incompatible state tort law is manifest in the regulatory scheme. Their opponents maintain that preemption of tort law would leave many vaccine victims without a remedy. Decisions on the issue of preemption have been as inconsistent as decisions on substantive issues of liability.

III. The Role of Preemption in the Vaccine Controversy

Underlying the crisis in vaccine litigation is the tension between state and federal power inherent in the federalist system. The function of state tort law in vaccine injury cases it to provide remedies for innocent victims. Contagious diseases do not respect state boundaries, however, and the states acting separately cannot control the spread of disease.[171] Although health and safety regulation is traditionally reserved to the states, pertussis and other childhood diseases have become a national concern out of necessity. Congress, therefore, promotes a policy of widespread immunization and strict regulation of the vaccine industry in conjunction with this policy. When federal policy objectives and state tort remedies clash, national public health interests as well as vaccine manufacturers are affected.

A. Preemption Doctrine

Congress has the power to override, or preempt, state law under the Supremacy Clause of the United States Constitution.[172] When Congress enacts legislation which is "necessary and proper"[173] to implement one of its plenary powers, any state law which conflicts with the federal law is preempted.[174] The Supremacy Clause thus enables Congress to

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171. In a statement on the Communicable Disease Control Amendments Act of 1972, Pub. L. No. 92-449, 86 Stat. 748, the Senate Committee on Labor and Public Welfare observed: "A further lesson learned in the history of disease control in the United States is the national scope of the threat posed by these diseases. By their very transmissible nature, communicable diseases know no geographic boundaries. Local control efforts are futile in the absence of a nationally coordinated effort." S. Rep. No. 825, 92d Cong., 2d Sess. 4, *reprinted in* 1972 U.S. Code Cong. & Admin. News 3430, 3433.

172. Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 152 (1982); Gibbons v. Ogden, 22 U.S. (9 Wheat.) 1 (1824). *See supra* note 7.

173. U.S. Const. art. I, § 8, cl. 18.

174. *See generally* D. Engdahl, Constitutional Federalism 74-78 (2d ed. 1987); J. Nowak, R. Rotunda & J. Young, Constitutional Law 292-94 (2d ed. 1983). The FDCA and PHSA were enacted pursuant to the commerce power. Hurley v. Lederle Laboratories, 651 F. Supp. 993, 1004 (E.D. Tex. 1986), *rev'd*, 851 F.2d 1536 (5th Cir. 1988).

address problems of national dimension by precluding state authority to act in particular areas and supplanting it with comprehensive federal legislation. Although Congress may expressly prohibit parallel state legislation, it rarely articulates such specific intent. "Savings" clauses which legitimize concurrent state regulation are more common in federal statutes than express prohibitions.[175] Absent a provision to the contrary, however, preemptive intent may be implicit in the legislative scheme even if Congress has failed to consider the preemptive effect of its legislation.[176]

The doctrine of implied preemption has emerged from federal jurisprudence. When the relationship between state and federal law is not clear from the statute or evident in the legislative history, the judiciary is called upon to discover congressional intent and invalidate state laws which are impliedly preempted. There is no rigid formula to guide judicial decisions because preemption issues are fact specific and arise in a broad range of subject matters.[177] The Supreme Court has cautioned that "prior cases on pre-emption are not precise guidelines . . . for each case turns on the peculiarities and special features of the regulatory scheme in question."[178]

The purpose of preemption is to preserve the supremacy of federal law and to prevent conflicting regulation by various sources of authority.[179] State common law, therefore, is subject to preemption in the same manner as statutes and regulations if it is regulatory in effect.[180] State law can be preempted by federal regulation as well as by federal statutes,[181] if congressional intent to preempt can be discovered in the

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175. J. Nowak, R. Rotunda & J. Young, *supra* note 174, at 292.

176. Hirsch, *Toward a New View of Federal Preemption*, 1972 U. Ill. L.F. 515, 542. The author notes: "Questions of the relation of the federal law to existing and potential state laws are seldom considered in detail in the drafting of federal legislation. Consequently, many federal acts are adopted without serious consideration of their impact on state laws dealing directly with the same subject matter." *Id.*

177. Note, *The Burger Court and Preemption Doctrine: Federalism in the Balance*, 60 Notre Dame L. Rev. 1233, 1234 (1985).

178. City of Burbank v. Lockheed Air Terminal, Inc., 411 U.S. 624, 638 (1973).

179. J. Nowak, R. Rotunda & J. Young, *supra* note 174, at 293.

180. The Supreme Court acknowledged in 1959 that state tort law is also subject to preemption:

> The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy. Even the States' salutary effort to redress private wrongs or grant compensation for past harm cannot be exerted to regulate activities that are potentially subject to the exclusive federal regulatory scheme.

San Diego Bldg. Trades Council v. Garmon, 359 U.S. 236, 247 (1959) (National Labor Relations Act precludes states from granting tort awards for damages arising out of conduct which comes within scope of Act). *See also* Int'l Paper Co. v. Ouellette, 479 U.S. 481, 498 (1987) (state tort law preempted regardless of whether its purpose was compensatory or regulatory).

181. Hillsborough County, Fla. v. Automated Medical Laboratories, Inc., 471 U.S.

regulatory scheme. When congressional intent is unclear, the courts must determine how much tension between state and federal law the system can bear.

Federal law is supreme only in those areas which are legitimate federal concerns. In recent years, the Supreme Court has pursued a policy of protecting the states from excessive federal power.[182] The Court has refused to preempt state regulation of local interests unless it interferes with the legitimate exercise of federal power. Through this *ad hoc* balancing of federal and state interests, federal case law has developed a framework of preemption analysis. There are two basic types of implied preemption: "occupation of the field" preemption and "conflict" preemption.

Under the first theory, federal law displaces state regulation entirely when Congress occupies the field with its regulatory scheme.[183] This comprehensive type of preemption is inconsistent with balanced federalism because it leaves no room at all for state law. Courts are reluctant to infer broad preemption absent a clear and manifest expression of congressional intent.[184] Judicial misinterpretation of unexpressed congressional intent could result in an inappropriate usurpation of state power at a time when the Supreme Court is particularly concerned with curbing the excesses of federal power. Consequently, a presumption against preemption must be overcome before a federal court will infer that Congress intended to occupy an entire field.[185]

The second type of implied preemption occurs when the state regulation conflicts with federal law and on precise point. The Court has been more willing to find conflict preemption than occupation of the field preemption because the former involves a subject on which Congress specifically has legislated and preemption is possible without precluding all state regulation in the area.[186]

B. DPT Vaccine Regulation and Implied Preemption

The preemption issue in vaccine cases arises primarily in relation to strict liability claims. Manufacturers argue that federal regulation of DPT design, production and labeling occupies the field and cannot be sup-

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707, 713 (1985); Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 153-54 (1982).

182. Note, *supra* note 177, at 1238.

183. Pennsylvania v. Nelson, 350 U.S. 497, 502-05 (1956).

184. Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947).

185. *Hillsborough County, Fla.*, 471 U.S. at 715 (1985); Maryland v. Louisiana, 451 U.S. 725, 726 (1981). *See also* Palmer v. Liggett Group, Inc., 633 F. Supp. 1171, 1173 (D. Mass. 1986), *rev'd*, 825 F.2d 620 (1st Cir. 1987).

186. Note, *supra* note 177, at 1254.

plemented by state tort law without frustrating national public health policy.

FDA decisions concerning vaccine regulation are subject to the standard of judicial review commonly applied to agency actions. The inquiry of courts always is limited when a federal agency acting within its statutory authority promulgates regulations. If an administrator's decision to preempt state law represents a reasonable choice between conflicting policies, a court will not disturb that choice "unless it appears from the statute or its legislative history that the accommodation is not one that Congress would have sanctioned."[187] The FDA regulates every aspect of DPT design, manufacture, testing, labeling, and distribution. Congressional approval of this regulatory scheme is implicit in the consistent renewal of immunization grant programs which promote the use of whole-cell DPT vaccine. This is the basis for arguments favoring broad preemption of tort liability for vaccine injuries.

Health and safety are traditionally state concerns, however, and specific vaccination policies are established by the states. Courts, therefore, require more than mere congressional acquiescence to overcome a strong presumption against congressional intent to displace state law entirely in the field of vaccine regulation.[188]

Federal case law has established four factors which must be considered in an occupation of the field analysis:

> (1) The aim and intent of Congress as revealed by the statute itself and its legislative history; . . .
> (2) The pervasiveness of the federal regulatory scheme as authorized and directed by the legislation and as carried into effect by the federal administrative agency . . . ;
> (3) The nature of the subject matter regulated and whether it is one which demands "exclusive federal regulation in order to achieve uniformity vital to national interest" . . . ; or,
> (4) "Whether, under the circumstances of a particular case, state law stands as an obstacle to the accomplishment and execution of the full purpose and objectives of Congress."[189]

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187. United States v. Shimer, 367 U.S. 374, 383 (1961), *quoted in* Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 154 (1982).

188. *See, e.g.*, Abbot v. American Cyanamid Co., 844 F.2d 1108 (4th Cir. 1988); Martinkovic v. Wyeth Laboratories, Inc., 669 F. Supp. 212 (N.D. Ill. 1987); Graham v. Wyeth Laboratories, 666 F. Supp. 1483 (D. Kan. 1987); MacGillivray v. Lederle Laboratories, 667 F. Supp. 743 (D.N.M. 1987); Jeski v. Connaught Laboratories, Inc., Civ. No. A-84-CA-395, mem. (W.D. Tex. Dec. 18, 1986); Smith v. Wyeth Laboratories, Inc., Civ. No. 84-2002, mem. (S.D.W. Va. Aug. 21, 1986).

189. Hurley v. Lederle Laboratories, 651 F. Supp. 993, 997 (E.D. Tex. 1986) (quoting Northern States Power Co. v. Minnesota, 447 F.2d 1143, 1146-47 (8th Cir. 1971), *aff'd*,

This type of preemption analysis first looks to the statute and its legislative history to discover congressional intent. Vaccine regulations are promulgated under authority of the Public Health Service Act (PHSA),[190] which provides for licensing of vaccine products, and the Food, Drug and Cosmetic Act (FDCA),[191] which was enacted to protect the public health by regulating the transportation of food and drugs in interstate commerce. Neither the language nor the legislative histories of the PHSA and FDCA reveal congressional intent to preempt state regulation of DPT manufacture and labeling.

Preemption is not precluded, however, merely because Congress failed to express preemptive intent when the regulatory scheme was first enacted.[192] Because the test is conjunctive, any one of the four factors of occupation of the field analysis may be sufficient to justify a finding of preemption. The controversy in vaccine litigation focuses on the latter three factors: the pervasiveness of the regulatory scheme, the dominant federal interest in uniform vaccine design and distribution, and the harmful impact of tort judgments on the national objective to ensure adequate production and supply to DPT vaccine.

The second test of broad preemption requires a scheme of federal regulation so pervasive as to permit a reasonable inference that Congress left no room for concurrent state regulation.[193] Federal vaccine regulation arose from the need to protect the public from unsafe biological products. Until the beginning of the twentieth century, biologics were manufactured and distributed without government testing or control. In 1902, fourteen children died from tetanus after receiving diphtheria antitoxin prepared from the serum of horses infected with tetanus.[194] Congress responded to this tragic incident with the Virus, Serum, Toxin Act of 1902,[195] which vested control over biological products used in interstate commerce in

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405 U.S. 1035 (1972)), *rev'd*, 851 F.2d 1536 (5th Cir. 1988). *See also* KVUE, Inc. v. Austin Broadcasting Corp., 709 F.2d 922, 931-32 (5th Cir. 1983), *aff'd sub nom.* Texas v. KVUE, Inc., 465 U.S. 1092 (1984).

190. Pub. L. No. 78-410, 58 Stat. 682 (1944) (codified as amended at 42 U.S.C. §§ 201-405 (1982)).

191. Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-392 (1982)).

192. Cosmetic, Toiletry & Fragrancy Ass'n v. Minnesota, 440 F. Supp. 1216, 1221 (D. Minn. 1977), *aff'd*, 575 F.2d 1256 (8th Cir. 1978).

193. *See* Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 153 (1982); Pennsylvania v. Nelson, 350 U.S. 497, 502 (1956).

194. *See* Esber, Meyer, Petricciani & Meyer, *The Role of the Food and Drug Administration in the Regulation of Biological Products*, *reprinted in* PROCEEDINGS OF THE 19TH IMMUNIZATION CONFERENCE, CENTERS FOR DISEASE CONTROL, 91 (1984).

195. Pub. L. No. 57-244, 32 Stat. 728.

the research branch of the Public Health Service (PHS). This branch later became the National Institute for Health (NIH).

In 1944, Congress incorporated the 1902 Act into the PHSA, which provided a framework for governmental control over biologics. The basic element of control was federal licensure of biological products and manufacturing facilities. The federal government was empowered to regulate product design, contents, testing, and labeling, to inspect manufacturing facilities, and to oversee the manufacturing process. The PHSA also authorized the federal government to manufacture biologics, but most vaccines continue to be produced by private business.[196]

The need for a stronger, expanded regulatory organization in the area of vaccines was recognized in 1955 when safety testing failed to disclose a flaw in a new polio vaccine and several children developed poliomyelitis after vaccination.[197] The Division of Biologics Standards[198] was established for this purpose and became responsible for setting federal standards for vaccine safety, purity and potency.

An expert review panel was formed in 1972 to evaluate all vaccines licensed in the United States and assure that they were safe, effective and properly labeled.[199] Concurrent with the panel's report in 1985, the FDA issued a proposed rule recognizing that the current whole-cell pertussis vaccine meets all licensing requirements and is safe and effective.[200]

Vaccines and other biological products are subject to much stricter regulation than drugs and nonbiological products. The FDA inspects each biologic manufacturing facility before issuing an establishment license.[201] Manufacturers are required to test each lot of vaccine using specific tests formulated by the FDA[202] and to submit the results together with a vaccine sample from each lot to the FDA for review and possible further testing before it is released for sale.[203] No comparable requirements

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196. Esber, Meyer, Petricciani & Meyer, *supra* note 194, at 91.

197. *Id.* at 91.

198. In 1972, this Division was transferred to the FDA and renamed the Bureau of Biologics. 37 Fed. Reg. 12,865 (1972). It later changed its name again to the Office of Biologics Research and Review. 49 Fed. Reg. 23,834 (1984). Together with the Bureau of Drugs, it now forms the FDA's Center for Drugs and Biologics and continues to be responsible for vaccine regulation. Esber, Meyer, Petricciani & Meyer, *supra* note 194, at 91.

199. 21 C.F.R. § 601.25 (1988).

200. *Biologics Review*, *supra* note 92, at 51,041-43.

201. 21 C.F.R. § 601.10(a) (1988).

202. 21 C.F.R. § 610 subparts A and B (1988).

203. 21 C.F.R. §§ 610.1-.2 (1988). In Berkovitz v. United States, 108 S. Ct. 1954 (1988), the Court held that the discretionary function exception does not bar an action alleging a federal agency's negligence in licensing a polio vaccine without first determining

exist for drugs. Particular tests of potency and toxicity are required for each vaccine,[204] and the manufacturer may not disregard, substitute, or vary the tests.[205] Any modification of testing or manufacturing methods must have prior FDA approval.[206] The FDA periodically inspects manufacturing facilities to ensure conformance to both the regulations and the manufacturer's stated method of production.[207] This comprehensive scheme also extends to labeling of vaccines. Language in the package insert must be approved by the FDA.[208] Labeling must warn of known hazards derived from human experience, not theoretical possibilities.[209]

Every aspect of vaccine design, testing, manufacture, and labeling is within the scope of federal regulation. The manufacture and sale of any vaccine other than that approved by the FDA in any manner other than that prescribed by the FDA would be a criminal offense under the FDCA.[210] Tort judgments imposing liability for the failure to market an alternative vaccine essentially penalize manufacturers for not committing a federal offense. The pervasiveness of federal regulation of the vaccine industry thus permits the inference that the federal regulatory scheme leaves no room for supplementation by inconsistent judicial mandates.

Nonetheless, courts are reluctant to find preemption on this basis. In *Graham v. Wyeth Laboratories*,[211] the court conceded the comprehensive nature of federal vaccine regulation but was unwilling to conclude that FDA rules and regulations were intended to exempt manufacturers altogether from tort liability.[212] It cited the 1986 Vaccine Act as evidence of congressional intent to preserve civil tort remedies despite pervasive

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the manufacturer's compliance with federal safety standards. Federal regulations empower but do not require the reviewing agency to test each vaccine lot submitted for approval by a manufacturer. *Id.* at 1963. If the agency has adopted a policy of testing all vaccine lots, however, employees who fail to implement this policy and knowingly release a lot without testing it for compliance with safety standards are not exercising policy judgments. *Id.* at 1964. Whether such a policy exists is a question of fact. *Id.*

204. 21 C.F.R. Part 620 and Part 630 (1988). Part 620 deals with bacterial vaccines and Part 630 with viral vaccines. Subpart A of Part 620 provides specific tests for pertussis vaccines.

205. 21 C.F.R. §§ 620.4-.5 (1988).

206. 21 C.F.R. § 610.9 (1988).

207. 21 C.F.R. § 600.20 (1988).

208. 21 C.F.R. § 601.12 (1988).

209. 21 C.F.R. §§ 201.56(c), 201.57(d) (1988). The FDA reviews product labeling regularly to assure that the most current and authoritative information is included in package inserts. *Biologics Review*, *supra* note 92, at 51,108.

210. *See* 21 U.S.C. §§ 331(d), 333(a), 355(a) (1982). *See also* Toner v. Lederle Laboratories, 779 F.2d 1429, 1431 (9th Cir. 1986).

211. 666 F. Supp. 1483 (D. Kan. 1987).

212. *Id.* at 1491.

federal regulation.[213] In *Hurley v. Lederle Laboratories*,[214] the Fifth Circuit Court of Appeals found that, because the ultimate effect of preemption on vaccine use was uncertain, "the decision to preempt state law products liability would be a difficult one for a policy-maker and it is not appropriate for us to assume that decision has been made based on such inconclusive evidence."[215] The court also cited the Vaccine Act as proof that Congress did not intend to preempt state tort law in this area.[216]

Many courts cite as controlling a 1985 Supreme Court pronouncement that extensive regulation does not necessarily preempt state tort law in the public health field. In *Hillsborough County, Florida v. Automated Medical Laboratories, Inc.*,[217] the Court noted: "Given the presumption that state and local regulation related to matters of health and safety can normally coexist with federal regulations, we will seldom infer, solely from the comprehensiveness of federal regulations, an intent to pre-empt in its entirety a field related to health and safety."[218] Specifically, the Court held that federal regulations governing the collection of blood plasma from paid donors did not preempt local ordinances requiring additional blood testing and record-keeping.

Despite the Court's preference for dual regulation in this area, the *Hillsborough* decision is not necessarily controlling in DPT cases due to the fact-specific nature of preemption. The local interest in blood collection is strong, whereas infectious disease control is necessarily a national concern. In addition, tort judgments in DPT cases may require manufacturers to do what the FDA forbids, unlike the local ordinances in *Hillsborough* which supplemented federal regulations without contradicting them. Finally, when the FDA first promulgated its blood collection regulations in 1973, it expressly stated that they were not intended to be exclusive and has never disavowed that intent.[219] The FDA has not expressed a similar intent with regard to vaccine regulation and has consistently refused to license any design other than whole-cell DPT vaccine.

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213. *Id.* at 1492. *See also* Morris v. Parke, Davis & Co., 667 F. Supp. 1332 (C.D. Cal. 1987); Patten v. Lederle Laboratories, 655 F. Supp. 745 (D. Utah 1987).

214. 851 F.2d 1536 (5th Cir. 1988).

215. *Id.* at 1540.

216. *Id.*

217. 471 U.S. 707 (1985).

218. *Id.* at 718. *See also* Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 249 (1984). In one DPT case, a judge who initially had found occupation of the field preemption prior to the *Hillsborough* decision, subsequently reconsidered his ruling in light of *Hillsborough*'s preemption analysis and reversed his opinion to find no preemption. Morris v. Parke, Davis & Co., 667 F. Supp. 1332, 1336-39 (C.D. Cal. 1987).

219. 471 U.S. at 714, 716.

The need for uniformity is the second factor in occupation of the field preemption. If the need for national uniformity demands exclusive federal regulation of a particular field, courts will assume that the federal system precludes enforcement of state laws on the same subject.[220] The purpose of regulation by one source is to assure the safety and efficiency of DPT vaccine and thus prevent the spread of pertussis on a national scale. The strong federal interest in uniform vaccine design and manufacture is evident in the FDA's refusal to approve an alternate type of DPT vaccine.[221] Even Massachusetts and Michigan, which manufacture their own DPT vaccine, are subject to the same FDA licensing requirements as private manufacturers.[222] Uniform labeling is also an established FDA policy.[223] The FDA's insistence on uniform design and labeling supports the proposition that vaccine regulation is an exception to the general rule that health and safety matters are local concerns. As the district court in the *Hurley* case noted, Congress enacted the FDCA and PHSA because "the states had not properly exercised the power reserved to them. . . . The use of DPT vaccine has been one way to accomplish the protection of public health and safety."[224]

Federal funding and support of local immunization programs provide further evidence of the dominant federal interest in the use of whole-cell DPT vaccine. The CDC provides technical assistance to state and local health departments in the form of regional public health advisors and administers the federal grant program begun under the Vaccination Assistance Act of 1962.[225] Under this program the federal government

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220. *See* Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 153 (1982); Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947).

221. In 1986, the FDA addressed the need for national uniformity in this area:

> FDA is authorized to assure the safety of drugs marketed in interstate commerce in this country. The manufacturing and distribution system for these products is national in scope and the measures adopted by FDA to regulate this national system should be adequate to safeguard the interests of the entire population. While State and local requirements for products may on occasion be appropriate and necessary, such measures should not interfere with FDA's accomplishing those purposes that are within its Congressionally mandated area of responsibility.

51 Fed. Reg. 8181 (1986).

222. *Biologics review*, *supra* note 92, at 51,104.

223. "FDA has a well-established policy of promoting uniformity in the area of labeling. . . . This preference for uniformity is also recognized by the judiciary in its construction of the Supremacy Clause of the United States Constitution." 50 Fed. Reg. 51,403 (1985).

224. Hurley v. Lederle Laboratories, 651 F. Supp. 993, 1004 (E.D. Tex. 1986), *rev'd*, 851 F.2d 1536 (5th Cir. 1988). The dual goals of the FDCA were to regulate the interstate transportation of food and drugs and to protect the public health. *Id. See also* United States v. Lee, 131 F.2d 464, 466 (7th Cir. 1942) (the FDCA was intended to protect the public health and to prevent fraud).

225. Immunization Grant Program, 42 U.S.C. § 247b (1982).

purchases DPT vaccine directly from the manufacturers and makes it available at a reduced price to state health departments for distribution in local public health clinics.

The CDC has developed an "Important Information Statement" which discusses the ACIP's recommendations concerning the risks and benefits of whole-cell pertussis vaccine. Officials at public health clinics are required to provide this statement to vaccinees or their parents before any vaccine purchased through the federal program is administered.[226]

Today, all but nine states require immunization against pertussis and rely on federal support to carry out this policy through local public health clinics.[227] The stated goal of the federal grant program is to make "immunization for vaccine-preventable childhood diseases available to every child in the United States."[228] The CDC's objective in administering the program is to achieve immunization against pertussis and other childhood diseases in over ninety percent of young children.[229]

Although the statistics appear to support the dominance of the federal interest in whole-cell DPT, some courts have reached the opposite conclusion. In *Jeski v. Connaught Laboratories, Inc.*,[230] the court found no uniform national policy regarding DPT vaccine use because nine states do not require vaccination against pertussis.[231] The *Jeski* court emphasized that universal childhood immunization is merely recommended, not required, by the federal government, and a statement of goals in the Federal Register is insufficient to establish a uniform national policy.[232]

In *Hurley*, the Fifth Circuit Court of Appeals attributed the absence of approved alternative vaccines to the manufacturer's failure to come forward with new formulas.[233] Characterizing the FDA as a "passive agency" which only acts upon proposals placed before it, the court held that there was "no basis for finding a federal interest in a particular form of the pertussis vaccine."[234] This reasoning ignores the federal government's active participation in the development of safer vaccines and the FDA's stated intent not to license any new formula until these efforts have produced satisfactory results.[235]

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226. U.S. Brief, *supra* note 32, at 19. This statement is also available to private physicians on request. *Id.*

227. *See supra* note 72.

228. 48 Fed. Reg. 9580 (1983).

229. 45 Fed. Reg. 12,491 (1980).

230. Civ. No. A-84-CA-395, mem. (W.D. Tex. Dec. 18, 1986).

231. *Id.* at 4.

232. *Id.* at 3. *See Biologics Review*, *supra* note 92, at 51,109.

233. Hurley v. Lederle Laboratories, 851 F.2d 1536, 1540 (5th Cir. 1988).

234. *Id.*

235. *See supra* text accompanying notes 102-04.

The *Graham* court recognized a strong federal interest but preferred to wait for a clear statement of congressional intent before finding that federal regulations "have preempted the ability of states to protect their citizens through the judicial process."[236] The absence of a federal remedy for vaccine victims prior to the Vaccine Act of 1986 strengthens the view that Congress did not intend to occupy the entire field of vaccine regulation despite its policy of widespread immunization.

Notwithstanding the absence of a federal remedy, preemptive intent may be inferred if state law impedes the accomplishment of legitimate federal objectives. This fourth test of broad preemption is satisfied if federal efforts to ensure vaccination of virtually all American children will be frustrated by jury determinations that the only approved vaccine is defective. Tort judgments already have threatened the availability of sufficient DPT vaccine to carry out immunization programs.

A shortage in the supply of DPT vaccine occurred in 1984 due to production problems and manufacturers' inability to obtain acceptable liability insurance coverage.[237] The ACIP and the Red Book Committee of the American Academy of Pediatrics were forced to recommend postponing the final two doses in the immunization schedule until increased supplies became available.[238] In response to this experience, the CDC undertook to build a federal stockpile of four million doses, approximately a six months' supply.[239] During a less serious shortfall in 1986, the CDC distributed between 800,000 and 900,000 of the one million doses of DPT vaccine then in its stockpile.[240] The federal government is seriously concerned that a vitally important vaccine, strongly recommended by public health authorities, may become unavailable before researchers can produce an acceptable alternative.[241]

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236. Graham v. Wyeth Laboratories, 666 F. Supp. 1483, 1491 (D. Kan. 1987).

237. H.R. REP. No. 908, 99th Cong., 2d Sess. 607, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS 6344, 6347-48. *See also* David, *supra* note 33, at 399.

238. Peter, *supra* note 3, at 981.

239. U.S. Brief, *supra* note 32, at 20.

240. *Id.* at 20 n.14.

241. *Id.* at 21. *See also* Abbot v. American Cyanamid Co., 844 F.2d 1108, 1116-17 (4th Cir. 1988) (Wilkins, J., concurring). Judge Wilkins found this preemption argument convincing and rejected complete preemption of tort liability only because the 1986 Vaccine Act expressly preserved certain aspects of state tort law:

> The withdrawal of any manufacturer from the market poses a serious threat to public health, in the form of vaccine shortages with resulting decreased immunization and a possible resurgence of these diseases.
>
> Under these circumstances alone, preemption would be warranted because state tort actions for design and warning defects stand as an obstacle to a major federal purpose.

Id.

Congress has delegated to the FDA exclusive authority to approve and license vaccines. A federal agency has the expertise to evaluate the safety and efficacy of products which lay persons do not possess. To permit a jury to hold a manufacturer liable for not making an FDA-rejected vaccine defeats the purpose of the regulatory scheme enacted by Congress. The district court in *Hurley* found this rationale persuasive,[242] but other courts disagree. Some find that tort actions may enhance the national goal of vaccine safety by encouraging manufacturers to accelerate their efforts to develop safer vaccines.[243] Another view is that the cost of compensating vaccine victims may not drive manufacturers out of the market at all if the federal government as a major purchaser bears the burden of higher prices.[244]

Even if the tests for complete preemption of tort liability for vaccine injuries are not met, federal regulation of the vaccine industry may preempt certain aspects of state tort law under the second type of implied preemption analysis. Conflict preemption does not require the total displacement of state law in a particular field but preempts state regulation narrowly on particular points. An actual conflict exists when compliance with both state and federal laws is impossible.[245] This situation affords a court more discretion than occupation of the field preemption because it allows the court to decide how much tension between state and federal law is tolerable before an actual, or irreconcilable, conflict arises.[246]

Conflict preemption also occurs when state law poses an obstacle to the accomplishment of congressional objectives.[247] The focus in obstacle

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242. Hurley v. Lederle Laboratories, 651 F. Supp. 993, 1005 (E.D. Tex. 1986), *rev'd*, 851 F.2d 1536 (5th Cir. 1988). The district court observed:

> A state common law determination that DPT design and manufacture is defective will seriously and irreconcilably conflict with the federal regulatory scheme and the national policies of immunization, adequate production, and supply of DPT. In effect, it will chill the efforts of the federal government to ensure that all U.S. children are immunized and frustrate Congress' intent in fostering such programs.

Id. at 1006.

243. Graham v. Wyeth Laboratories, 666 F. Supp. 1483, 1493 (D. Kan. 1987); MacGillivray v. Lederle Laboratories, 667 F. Supp. 743, 745 (D. N.M. 1987).

244. Hurley v. Lederle Laboratories, 851 F.2d 1536, 1540 (5th Cir. 1988).

245. Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142-43 (1963). *See also* California Coastal Comm'n v. Granite Park Co., 480 U.S. 572, 580 (1987); California Fed. Sav. & Loan Ass'n v. Guerra, 479 U.S. 272, 280 (1987).

246. In Silkwood v. Kerr-McGee Corp., 464 U.S. 238 (1984), for example, the tension between the exclusive federal interest in safety regulation of nuclear plants and state damages awards for injury when safety standards are violated did not require preemption of state law. The Court concluded that "Congress intended to stand by both concepts and to tolerate whatever tension there was between them. We can do no less." *Id.* at 256.

247. Hines v. Davidowitz, 312 U.S. 52, 67 (1941). *See also* Hillsborough County,

conflict cases is on the federal law's purpose and objectives rather than preemptive intent. The court first determines what the federal objectives are and then balances state and federal interests. If the state interest is strong and only the potential for conflict exists, the state regulation may stand.[248] State law is preempted, however, if it cannot be reconciled with the legitimate exercise of federal power. In obstacle conflict cases, either federal objectives have been frustrated by state law or a conflict is inevitable.[249]

The Supreme Court has applied a conflict preemption analysis to each provision of a state statute and preempted only those portions which conflicted with federal law or posed obstacles to federal objectives.[250] In this manner, the Court has deferred to overriding federal interests in uniform regulation while accommodating substantial state interests to the greatest extent possible. The Court will ignore local concerns, however, in order to protect the legitimate exercise of federal power.[251] In the context of the vaccine controversy, state policies established by judicial decision are also appropriate subjects for this selective approach to conflict preemption.

Tort awards based on liability for design defect and inadequate warning have produced most of the problems in vaccine litigation. Manufacturers can do little in response to adverse tort judgments for defective design and labeling until the FDA is prepared to change its position. In effect, juries assume the FDA's role of deciding whether an alternative design or additional information about risks meet the agency's standards. This is not a matter of supplementing minimum standards established by federal regulation with a higher standard of care. Negligence claims may survive conflict preemption if they do not

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Fla. v. Automated Medical Laboratories, Inc., 471 U.S. 707, 713 (1985); Pacific Gas & Elec. Co. v. State Energy Resources Conservation & Dev. Comm'n, 461 U.S. 190, 204 (1983).

248. *See, e.g.*, Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Ware, 414 U.S. 117 (1973) (state law permitting wage earners to sue and recover unpaid wages posed no real obstacle to federal law's objective to ensure fair dealing and protect investors from unfair trading practices despite wage earner's prior agreement under authority of federal law to arbitrate disputes arising from termination of employment).

249. Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141 (1982) (state law limiting ability of federal savings and loan associations to exercise due-on-sale clauses in mortgages posed obstacle to federal regulation's objective to ensure financial soundness of such associations through use of due-on-sale clauses).

250. Ray v. Atlantic Richfield Co., 435 U.S. 151 (1978) (federal statute regulating oil tanker design and operation preempted state provisions requiring state licensed pilots on basis of actual conflict and provisions regulating design standards as obstacle conflict, but did not preempt provision requiring tug escorts for tankers of substandard design because matter not addressed in the federal law).

251. *Fidelity Fed. Sav. & Loan Ass'n*, 458 U.S. at 153.

substantially impede the federal objective, but design defect and inadequate warning claims conflict directly with the regulatory scheme and frustrate the legitimate exercise of federal power. Uniform regulation is impossible when juries are allowed to substitute their lay judgment for the judgment of the FDA and the expertise of numerous public health authorities.[252]

In 1905, the Supreme Court rejected an attack on compulsory smallpox vaccination despite the plaintiff's evidence that smallpox vaccine was ineffective and harmful.[253] Noting that opinions may differ on issues of public health policy, Justice Harlan wrote:

> We must assume that when the statute in question was passed, the legislature of Massachusetts was not unaware of these opposing theories, and was compelled, of necessity, to choose between them. . . . It is no part of the function of a court or a jury to determine which one of two modes was likely to be the most effective for the protection of the public against disease. That was for the legislative department to determine in the light of all of the information it had or could obtain.[254]

In the case of vaccine regulation, Congress expressly delegated this function to the FDA. The Supreme Court affirmed Justice Harlan's view more recently in the context of the modern administrative state:

> "Evaluation of conflicting reports as to the reputation of drugs among experts in the field is not a matter well left to a court without chemical or medical background". . . . Threshold questions within the peculiar expertise of an administrative agency are appropriately routed to the agency, while the court stays its hand.[255]

The FDA regulates DPT labeling to promote uniformity and to ensure that the vaccine is accompanied by a complete and accurate explanation of its purpose and risks. The agency does not permit any statements about safety which may be misleading or are not supported by scientific evidence.[256] A state common law mandate to supplement

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252. There is also inherent tension when a state mandates the use of DPT vaccine and at the same time permits its courts to determine that the required vaccine is unsafe. *See supra* text accompanying note 169.

253. Jacobson v. Massachusetts, 197 U.S. 11 (1905).

254. *Id.* at 30.

255. Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645, 653-54 (1973) (quoting the district court opinion).

256. 44 Fed. Reg. 37,441 (1979). *See also* 40 Fed. Reg. 15,394 (1975); 39 Fed. Reg. 33,232 (1974).

the approved warning with information about other possible dangers will conflict with federal regulation if the additional information does not satisfy these labeling requirements. Furthermore, jury decisions in warning cases may turn on the testimony of the most convincing expert, and experts in the field do not agree on the safety and efficacy of alternative vaccine designs or on the degree of risk associated with whole-cell DPT. Consequently, manufacturers can never be certain whether their warnings are adequate for the next case.

Nevertheless, courts continue to assume a significant role in vaccine regulation. Many have rejected conflict preemption in vaccine cases on the basis of *Silkwood v. Kerr-McGee Corp.*,[257] in which the Supreme Court held that federal preemption of the safety aspects of nuclear energy does not extend to tort awards for conduct related to radiation hazards. The Court previously held in *Pacific Gas & Electric Co. v. State Energy Resources Conservation & Development Commission*[258] that the federal government occupied the entire field of nuclear safety in regulating the construction and operation of nuclear plants.[259] In *Silkwood*, the Court determined that the preempted field did not include state-authorized awards of punitive damages and that neither test of conflict preemption had been satisfied. Paying both state tort awards and federal fines imposed by the Nuclear Regulatory Commission for the same incident was not physically impossible. The tension between state and federal standards was tolerable and, therefore, did not constitute an actual conflict requiring preemption.[260] The exposure to damages in state tort actions for radiation injuries also did not frustrate the federal statutory objective of developing the use of nuclear energy for peacetime purposes.[261]

Vaccine litigation differs from the situation presented in *Silkwood* in one important respect. Karen Silkwood's radiation injuries were caused by the type of accident that federal regulations were designed to prevent. There was evidence that Kerr-McGee did not always comply with safety regulations,[262] which may have influenced the jury's decision to award punitive damages and the Court's decision to uphold the award. Federal regulation of DPT vaccine is designed to prevent pertussis, and the

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257. 464 U.S. 238 (1984) (preemption doctrine does not bar award of punitive damages for contamination injuries suffered by employee of federally licensed nuclear facility).

258. 461 U.S. 190 (1983) (state statute regulating nuclear waste disposal upheld despite federal regulation of safety aspects of nuclear power because state's purpose was economic and not to regulate safety).

259. *Id.* at 212.

260. 464 U.S. at 256-57.

261. *Id.* at 257.

262. *Id.* at 243.

federal government encourages the use of whole-cell DPT for this purpose despite its known and unavoidable risks. DPT manufacturers are subject to substantial liability, without any implication of wrongdoing, for injuries which federal regulations fully contemplated.

The presumption against preemption of state law prevailed in *Silkwood* primarily because Congress had failed to provide a federal remedy for injuries caused by nuclear hazards. Justice Blackmun, who dissented from the Court's holding on the issue of punitive damages, agreed with the majority that it was "inconceivable that Congress intended to leave victims with no remedy at all."[263]

Some courts have been reluctant to exempt vaccine manufacturers from state tort liability for the same reason—the federal regulatory scheme does not address remedies available to those injured by DPT vaccine.[264] Applying the *Silkwood* precept that a certain degree of tension must be tolerated, these courts have adopted the position that Congress did not intend to leave vaccine victims without a remedy and that it is not impossible for manufacturers to comply with federal standards and pay for whatever injury results. Under this view, the purpose of tort liability for vaccine-related injury is not regulatory but remedial and compensatory in nature, and state tort law, therefore, does not conflict irreconcilably with federal standards or frustrate federal objectives.

The Supreme Court recently adopted a two-part approach to conflict preemption which is somewhat broader than the *Silkwood* standard of intolerable or irreconcilable conflict between federal law and state law. *Boyle v. United Technologies Corp.*[265] involved the imposition of liability on a government contractor for defective design of a helicopter escape hatch which was manufactured to the precise specifications of the contract. The first part of the *Boyle* test requires a "uniquely federal interest"

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263. *Id.* at 263 (Blackmun. J., dissenting). Justice Blackmun and Justice Powell, who also dissented, believed that only compensatory damages survived the federal law's preemptive effect. *Id.* at 264, 276.

264. In Wack v. Lederle Laboratories, 666 F. Supp. 123 (N.D. Ohio 1987), the court rejected implied preemption of plaintiffs' design defect, inadequate warning, and punitive damages claims, noting that "such action would effectively deprive the plaintiffs of any civil remedy." *Id.* at 128. *See also* Jeski v. Connaught Laboratories, Inc., Civ. No. A-84-CA-395, mem. (W.D. Tex. Dec. 18, 1986). That court concluded:

> There is no evidence of a Congressional design to preempt state tort law remedies for persons injured by DPT vaccines. . . . Further, there is no evidence that it is necessary to disallow state tort remedies in order to achieve the goals of the applicable federal regulations. Finally, there is no evidence that the applicable federal regulations were designed or intended to provide immunity from state tort law to manufacturers who complied with the regulations.

Jeski, at 5.

265. 108 S. Ct. 2510 (1988).

which is so committed to federal control that federal law must displace state law.[266] The Court held that the liability of independent contractors who perform work for the federal government is a uniquely federal interest because the government will be affected directly whether such liability increases the price of the product or causes the contractor not to manufacture the design specified.[267] The second part of the test requires either a "significant conflict" between the federal interest or policy and state law, or the frustration of federal statutory objectives by state law.[268] In *Boyle*, the Court found that a significant conflict existed between the duty imposed by the contract to manufacture a specific type of mechanism and the state tort law duty of care which required a different design.[269] The choice of design was an exercise of a federal discretionary function which necessarily involved a "tradeoff between greater safety and greater combat effectiveness."[270] The Court concluded that "[i]t makes little sense to insulate the Government against financial liability for the judgment that a particular feature of military equipment is necessary when the Government produces the equipment itself, but not when it contracts for the production."[271]

The analogy to DPT vaccine cases is striking. There is a uniquely federal interest in nationwide immunization to prevent the spread of pertussis disease and in maintaining adequate supplies of vaccine in order to accomplish this objective. Because the federal government is a major purchaser of DPT vaccine, the financial burden of tort judgments against vaccine manufacturers would ultimately rest in substantial part on the United States itself. In *Boyle*, the Court was particularly concerned about the fiscal burden of contractors' liability.[272] In addition to the uniquely federal interest, there is a significant conflict between the obligation of vaccine manufacturers to produce the federally-mandated whole-cell design and the duty under state tort law to produce an alternate form. The decision to license a particular vaccine rests entirely with the FDA, and it makes no more sense to insulate these decision-makers from the liability which manufacturers must bear than it does in the context of government contractors.

It is noteworthy that the *Boyle* test requires only a significant rather than an irreconcilable conflict. Apparently, a lesser degree of tension

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266. *Id.* at 2514.
267. *Id.* at 2515.
268. *Id.*
269. *Id.* at 2516.
270. *Id.* at 2517. Discretionary functions of government actors are immune from liability under the Federal Tort Claims Act. 28 U.S.C. § 2680(a) (1982).
271. 108 S. Ct. at 2518.
272. *Id.*

will be tolerated where a uniquely federal interest is involved. The 1986 Vaccine Act and 1987 Vaccine Amendments are clear indications that the federal interest in mass immunization against childhood diseases is unique.

C. Preemption and the National Childhood Vaccine Injury Act of 1986

The 1986 Vaccine Act provided that certain tort remedies shall remain available despite the federal regulatory scheme. Congress acknowledged, however, that the tort system is not equipped to deal exclusively with the problems of vaccine-related injury. Explaining the need for legislation in this area, a House Committee report stated:

> [T]wo overriding concerns have led to the development of this legislation: (a) the inadequacy—from both the perspective of vaccine-injured persons as well as vaccine manufacturers—of the current approach to compensating those who have been damaged by a vaccine; and (b) the instability and unpredictability of the childhood vaccine market.[273]

In addition to providing a federal remedy, the Vaccine Act curtailed certain aspects of tort law which discouraged production of vaccines and interfered with the federal objective to achieve maximum protection against childhood diseases. The preemption debate centers on whether the Act's barriers to the recovery of damages in tort preclude or abrogate preemptive intent under pre-Act law.

The relationship contemplated by Congress between tort law and the federal scheme is disclosed in the compensation program. The United States Claims Court is responsible for deciding who is eligible and the amount of compensation to which each victim is entitled.[274] A Vaccine

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273. H.R. REP. No. 908, 99th Cong., 2d Sess. 7, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS 6344, 6348.

274. 42 U.S.C. § 300aa-12(a) (Supp. IV 1986). The Department of Health and Human Services is to administer payments authorized by the court. *Id.* § 300aa-10(a). The 1986 Act vested jurisdiction in the federal district courts. President Reagan initially objected to a court-administered entitlement program on the ground that it presented a potential separation of powers problem and because the federal judiciary was "a poor choice to ensure a well-managed and effective program." 22 WEEKLY COMP. PRES. DOC. 1565, 1566 (Nov. 14, 1986). The 1987 Vaccine Amendments changed the jurisdictional provision to its present form. Pub. L. No. 100-203, § 4307, 101 Stat. 1330-224 (1987). Jurisdiction in the Court of Claims, which has special expertise in handling claims against the United States, should provide for greater efficiency and more uniform application of the Act's standards for compensation. See 42 U.S.C. § 300aa-13 (Supp. IV 1986). Although the President would have preferred a program administered entirely by the executive branch, the Court of Claims was an acceptable alternative.

Injury Table limits coverage to three vaccinations currently mandated in most jurisdictions: DPT, OPV (oral polio), and MMR (measles, mumps, and rubella).[275] It further specifies types of injuries, disabilities, and other conditions covered by the program for each vaccine[276] and provides for modification of the Table upon proof that an unlisted injury is vaccine-related.[277]

There are two categories of claimants: those vaccinated before the Act's effective date and those vaccinated after the effective date. The latter may receive compensation for past and future actual expenses related to the injury, for loss of earnings both actual and anticipated, and for pain and suffering not to exceed $250,000.[278] If the vaccine was administered before the Act's effective date, claimants may be compensated only for actual expenses incurred after the date of the judgment.[279] Punitive damages are prohibited,[280] but an award of $250,000 may be made to the estate of a deceased.[281]

Despite limitations on the amount of compensation available for injuries suffered prior to the effective date, there is no limitation on the retroactivity of the program.[282] A person in this category may elect to bring a civil action rather than seek federal compensation, but filing an action after the effective date precludes any award under the program.[283] If damages are denied or the action is dismissed before the effective date, the claimant remains eligible for compensation.[284] Any person awarded damages either by judgment or settlement is ineligible for the program.[285] If a civil suit is pending when the program becomes effective, the claimant may withdraw the action and petition for compensation but is ineligible if he fails to withdraw the tort action within

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275. 42 U.S.C. § 300aa-14(a) (Supp. IV 1986).
276. *Id.*
277. *Id.* § 300aa-14(c).
278. *Id.* § 300aa-15(a).
279. *Id.* § 300aa-15(b).
280. *Id.* § 300aa-15(d).
281. *Id.* § 300aa-14(a)(2).
282. There are two limitations which may preclude some claimants from receiving compensation. After 3,500 petitioners have been compensated for injuries received before the Act's effective date, only persons vaccinated after the effective date will be eligible to file for compensation. *Id.* § 300aa-11(b). Compensation for injuries suffered before the effective date is to be paid in four equal annual installments, but if annual appropriations of $80 million are insufficient to meet payment obligations, the program's limitations on civil tort actions will no longer apply. *Id.* § 300aa-15(f). Furthermore, this portion of the program will cease to be effective when funds run out unless Congress appropriates additional funds beyond 1992. *See* text accompanying note 15.
283. 42 U.S.C. § 300aa-11(a)(6) (Supp. IV 1986).
284. *Id.* § 300aa-11(a)(4).
285. *Id.* § 300aa-11(a)(7).

two years after the effective date or before it terminates in a judgment.[286]

Persons injured by vaccines after the effective date of the Act are required to petition for compensation under the program before they may bring a civil action for damages.[287] After the Court of Claims issues a judgment either awarding or denying compensation, the claimant may elect to accept the judgment or file a civil action for damages.[288] Failure to file an election within ninety days is deemed acceptance of the judgment.[289] A claimant may not bring suit against a vaccine manufacturer after accepting a judgment under the program.[290]

The compensation program assures a more certain remedy than tort law,[291] but the incentive to opt for a civil action remains strong if juries are free to render multi-million dollar awards under varying theories of liability. The Act provides that state law shall govern civil actions arising from vaccine-related injuries,[292] but it imposes three modifications on the liability of manufacturers in cases where the vaccine was administered after the effective date.

First, Congress adopted the Restatement's comment k exception in the form of a government standards defense against claims of improper preparation and inadequate warning. A vaccine manufacturer cannot be held liable for unavoidable side effects if it complied in all material respects with federal manufacturing and packaging requirements.[293] Compliance merely creates a presumption of due care, however, which can be overcome by proof that a manufacturer wrongfully withheld information about its vaccine or failed to exercise due care despite its com-

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286. *Id.* § 300aa-11(a)(5).

287. *Id.* § 300aa-11(2). This requirement applies only if the damages sought exceed $1,000. *Id.*

288. *Id.* § 300aa-21(a).

289. *Id.*

290. *Id.*

291. However, compensation is not assured. The Act provides that petitions for compensation for post-effective date injuries (to be paid from the Trust Fund, *see supra* text accompanying note 16) will not be accepted if the number of compensation awards in three-month periods extending through September of 1992 exceeds specified limits for each period, and further that the limitations on civil actions shall not apply if petitions cannot be filed. *Id.* § 300aa-34.

292. 42 U.S.C. § 300aa-22(a) (Supp. IV 1986).

293. The Act provides:

> (1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this sub-part if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

Id. § 300aa-22(b).

pliance with FDA regulations.[294] Significantly, there is no mention of a defense to design defect claims. The second modification removes the judicially imposed requirement that manufacturers provide direct warnings to vaccine recipients.[295] Finally, the Act establishes a three-stage procedure for civil actions brought in lieu of federal compensation.[296] The issue of liability must be decided in the first stage before the amount of damages may be considered in the second.[297] In the third stage, a plaintiff may seek punitive damages but must prove wrongful conduct.[298]

These barriers should discourage tort actions and induce most vaccine victims to seek compensation under the federal program, yet tort remedies remain available in appropriate cases. Manufacturers will be able to predict litigation and compensation costs with more certainty, and the ultimate result should be a more stable childhood vaccine market.[299]

By preempting certain aspects of tort liability, Congress assumed that relief under these tort theories was available in pre-enactment cases and will continue to be available on a limited basis. Except for the limitations expressed, civil actions for vaccine-related injuries are to be governed by state law. Nowhere, however, does the Act expressly address the nature and extent of substantive tort law before the program's modifications.

It is significant that the Act does not limit the one aspect of tort law which conflicts directly and irreconcilably with the federal regulatory scheme. Design defect claims are the most controversial aspect of vaccine litigation because liability is founded on the manufacturer's failure to violate federal regulations. Clinical studies on the scale necessary to satisfy FDA requirements are too costly for any single manufacturer to undertake, particularly when there is no practical way to conduct them in this country. Contrary to the argument that tort liability provides manufacturers with an incentive to produce better vaccines, damages awards in the $15 million range for the negligent failure to change FDA policy are more likely to induce manufacturers to abandon the vaccine market altogether. Under a risk-benefit approach, strict liability for design defect assumes the feasibility of a better alternative. When the federal government allows only one vaccine design and manufacturers cannot provide acceptable proof of another design's safety and efficacy, no alternative is feasible.

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294. *Id.* The plaintiff must provide clear and convincing evidence of lack of due care rather than a mere preponderance of the evidence. *Id.*

295. *Id.* § 300aa-22(c).

296. *Id.* § 300aa-23(a).

297. *Id.* § 300aa-23(b)-(c).

298. *Id.* § 300aa-23(d).

299. Patten v. Lederle Laboratories, 655 F. Supp. 745, 749 (D. Utah 1986).

It is inconceivable that Congress would ignore the devastating effect of design defect claims when the express purpose of the Vaccine Act was to relieve the liability crisis and ensure an uninterrupted supply of childhood vaccines. Limitations on tort liability were imposed where necessary to further this national policy. Any recognition of liability for defective vaccine design would have been an admission that the regulatory scheme authorized by Congress had failed. It was not necessary for the Vaccine Act to address design defect claims if they were preempted by prior regulations promulgated under the FDCA and PHSA. Otherwise, Congress' failure to limit the most unpredictable and destructive aspect of tort liability would have frustrated its own objective.

IV. Conclusion

The Vaccine Act establishes that compliance with government standards is an affirmative defense to manufacturing and inadequate warning claims. The system can tolerate some tension when there is clear and convincing evidence that a manufacturer failed to exercise due care in the production and packaging of its vaccine despite compliance with federal standards. A government standards defense is an appropriate means to protect manufacturers without exempting them from fault-based liability where variations in the manufacturing process and labeling of vaccines are possible. Preemption of manufacturing defect and warning claims would have been improper and unnecessary.

Preemption is not a defense. Preemption of design defect claims does not arise because vaccine manufacturers complied with federal standards but because whole-cell DPT is the only vaccine licensed and approved for sale by the FDA in furtherance of the paramount federal objective of nationwide protection against infectious disease. The conflict becomes intolerable when a manufacturer is punished for the federal government's choice of design while the official agency charged with testing and approving that choice enjoys immunity.[300]

The clear purpose of the Vaccine Act was to make it easier for innocent victims to get compensation and to promote national public health policy by ensuring an adequate supply of the only approved vaccine while public and private interests together seek a safer alternative.

There is no evidence in the Vaccine Act or its legislative history of congressional intent to undo the preemptive effect of regulations promulgated under authority of the PHSA and FDCA. The effect of these

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300. One district court has suggested that responsibility for improper design or labeling of DPT vaccines "should rest with the official agencies charged with testing, approving and recommending them." Hurley v. Lederle Laboratories, 651 F. Supp. 993, 1008 (E.D. Tex. 1986), *rev'd*, 851 F.2d 1536 (5th Cir. 1988).

regulations was to preempt tort theories for design defect while leaving all other theories of recovery available. The Vaccine Act's specific limitations on tort liability reinforce the inference that Congress intended federal agencies to be solely responsible for policy decisions with regard to vaccine design. If Congress wanted the tort system to determine liability for design defects in lieu of no-fault compensation, it would have imposed limitations on recovery for design defect as it did on claims for manufacturing defects and inadequate warnings and on awards of punitive damages.

The Act's explicit restrictions on tort liability apply only after no-fault compensation has been rejected or becomes unavailable. Preemption of design defect claims does not leave plaintiffs without a remedy either before or after the Act's effective date because all other aspects of tort liability remain unaffected. Preemption of design defect claims does prevent tort law from placing manufacturers in an impossibility of performance situation and, together with the Act's limitations on other theories, makes manufacturers' liability more predictable and more insurable.

This narrow application of conflict preemption is entirely consistent with the provisions and intent of the Vaccine Act and with the Supreme Court's policy not to infringe on state power any more than necessary to protect dominant federal interests. The liability of manufacturers who meet the FDA's strict design specifications is a uniquely federal interest because the government's immunization policy is affected directly by resulting price increases and potential shortages of a vaccine which is vital to national immunization objectives. Furthermore, there is a significant conflict between the duty imposed by the FDA to manufacture nothing but the whole-cell vaccine and the duty imposed by state tort law to manufacture an alternative formula which the FDA has rejected. Preemption of design defect claims would help to alleviate the crisis in vaccine litigation and foster the national objective to prevent the spread of pertussis disease. It should be part of the substantive law a state must follow under the Supremacy Clause.

Peggy J. Naile

The Eleventh Amendment Controversy Continues: The Availability and Scope of Relief Against State Entities Under the Education of the Handicapped Act

I. Introduction

Historically, handicapped children have suffered not only from physical and mental limitations, but from a denial by society of educational opportunities which could help them achieve their maximum potential. It was not until 1975 that handicapped children received significant congressional recognition of their problems in the Education of the Handicapped Act (EHA or Act),[1] which was enacted "to assure that all handicapped children have available to them . . . a free appropriate public education."[2] The Act begins with findings that in 1970 there were more than eight million handicapped children in the United States, more than half of whom had special educational needs not being fully met.[3] The Act provides federal funds to state and local agencies to support their efforts in educating the handicapped; however, the Act conditions this assistance on the state's development of a policy and plan "that assures all handicapped children the right to a free appropriate public education."[4]

One of the basic purposes of the Act is to assure the protection of the rights of handicapped children and their parents or guardians.[5] Detailed procedural requirements are imposed upon the states to safeguard those rights.[6] These procedures include the right of the parents or guardians, and the child when appropriate, to have notice of and participate in the development and review of an individualized educational program (IEP) for the child. This IEP specifies instructional goals and objectives, and criteria for progress evaluation.[7] If the parents or the child decide this educational program is not adequate or appropriate, or if they feel their procedural rights have been infringed, they have a right to a hearing before the state educational agency.[8] Further, if any party is "aggrieved" by the findings and decision of this agency hearing, the Act grants a right to bring a civil action in federal or state court.[9]

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1. 20 U.S.C. §§ 1400-85 (1982 & Supp. 1985).
2. *Id.* § 1400(c).
3. *Id.* § 1400(b)(1)-(3).
4. *Id.* § 1412(1). *See* S. Rep. No. 168, 94th Cong., 1st Sess. 13, *reprinted in* 1975 U.S. Code Cong. & Admin. News 1425, 1437.
5. 20 U.S.C. § 1400(c) (1982).
6. *Id.* § 1415.
7. *Id.* § 1401(19); *See* Board of Educ. v. Rowley, 458 U.S. 176, 181 (1982).
8. 20 U.S.C. § 1415(c) (1982).
9. *Id.* § 1415(e)(2).

When a party has been aggrieved, the EHA directs a court to "grant such relief as the court determines is appropriate;"[10] however, the Act itself gives no explanation as to the meaning of "appropriate" relief.[11] This lack of congressional guidance has led to disagreement among the United States Circuit Courts of Appeals over the scope of relief available under the Act.[12] Included in this debate is the question of whether states are immune from suits in federal court for monetary relief under the Act in light of the Constitutional protections of the eleventh amendment.

In 1985, a case[13] reached the Supreme Court which involved a similar question of whether the eleventh amendment bars suits in federal court for monetary relief under Section 504 of the Rehabilitation Act of 1973.[14] The Court in *Atascadero State Hospital v. Scanlon* created an effective barrier to such suits under Section 504 by holding that "Congress must express its intention to abrogate" a state's eleventh amendment immunity "in unmistakable language in the statute itself."[15] This decision established a stringent standard for determining congressional intent before the eleventh amendment bar will be overridden.[16]

The strict standard of *Atascadero*, however, has failed to resolve the split among the federal circuits as to the applicability of the eleventh amendment to suits against states under the EHA.[17] A resolution of this

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10. *Id.*

11. "Absent other reference, the only possible interpretation is that the relief is to be 'appropriate' in light of the purpose of the Act. As already noted, this is principally to provide handicapped children with 'a free appropriate public education which emphasizes special education and related services designed to meet their unique needs.'" Burlington School Comm. v. Department of Educ., 471 U.S. 359, 369 (1985).

12. *See, e.g., id.* (resolved conflict among the circuits to hold that appropriate relief includes retroactive reimbursement to parents for their expenditures on private special education for the child if a court ultimately determines that such placement rather than a proposed program, is proper under the Act); Meiner v. Missouri, 800 F.2d 749 (8th Cir. 1986) (compensatory education appropriate under the Act as similar to reimbursement); Alexopulos v. Riles, 784 F.2d 1408 (9th Cir. 1986) (compensatory education not appropriate relief as identical to a request for damages).

13. Atascadero State Hosp. v. Scanlon, 473 U.S. 234 (1985).

14. 29 U.S.C. § 794 (1982 & Supp. 1985). This section provides:

> No otherwise qualified individual with handicaps in the United States . . . shall, solely by reason of this handicap, be excluded from the participation in, be denied benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance or under any program or activity conducted by any Executive agency or by the United States Postal Service.

15. *Atascadero*, 473 U.S. at 243.

16. *See* Doe *ex rel.* Gonzales v. Maher, 793 F.2d 1470, 1493-94 (9th Cir. 1986), *aff'd on other grounds sub nom.* Honig v. Doe, 108 S. Ct. 592 (1988); David D. v. Dartmouth School Comm., 775 F.2d 411, 417 (1st Cir. 1985), *cert. denied sub nom.* Massachusetts Dep't of Educ. v. David D., 475 U.S. 1140 (1986).

17. *See, e.g.*, Muth v. Central Bucks School Dist., 839 F.2d 113 (3d Cir. 1988)

intercircuit split is crucial because state agencies play significant roles in implementing the policies and programs of the Act.[18] Further, the states also make the determination in administrative proceedings of what constitutes appropriate educational programs.[19] Therefore, it is often a state agency's policy or determination which serves as the basis of a cause of action in federal court. To impose upon states affirmative duties to insure the rights provided for in the Act, while at the same time providing the states with immunity from breaches of those duties seems a contradictory result at best.[20]

This Note will first discuss the eleventh amendment, both from a historical perspective and through an analysis of the *Atascadero* decision. It will then review the types of relief available under the EHA and recent court decisions and statutory enactments which have clarified those types of relief, and it will analyze the availability of each type of relief against a state or state entity. It will also examine the conflicting approaches the courts of appeals have applied to the abrogation of state immunity in the EHA under the more rigorous rules of *Atascadero*. It is the central thesis of this Note that the eleventh amendment does not bar private suits for monetary relief under the *Atascadero* test, based upon the EHA's language and purpose.

II. Eleventh Amendment Doctrine

A. General Scope of Eleventh Amendment Immunity

The eleventh amendment provides:

(held the EHA authorizes suits against states in federal court for both injunctive and monetary relief); *David D.*, 775 F.2d 411 (same); *Maher*, 793 F.2d 1470 (held Congress did not abrogate eleventh amendment immunity in the EHA); Gary A. v. New Trier High School Dist. No. 203, 796 F.2d 940 (7th Cir. 1986) (same).

18. 20 U.S.C. § 1412(6) (1982 & Supp. 1985) provides:

> The State educational agency shall be responsible for assuring that the requirements of this subchapter are carried out and that all educational programs for handicapped children within the State, including all such programs administered by any other State or local agency, will be under the general supervision of the persons responsible for educational programs for handicapped children in the State educational agency and shall meet education standards of the State educational agency. This paragraph shall not be construed to limit the responsibility of agencies other than educational agencies in a State from providing or paying for some or all of the costs of a free appropriate public education to be provided handicapped children in the State.

19. *Id.* § 1415(c) (1982).

20. Congress stated in the preamble to the EHA:

> [I]t is in the national interest that the Federal Government assist State and local efforts to provide programs to meet the educational needs of handicapped children in order to assure equal protection of the law.

20 U.S.C. § 1400(b)(9) (1982).

> The Judicial Power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign State.[21]

The significance of this amendment "'lies in its affirmation that the fundamental principle of sovereign immunity limits the grant of judicial authority in Article III' of the Constitution."[22] The amendment restricts only the jurisdiction of federal courts.[23] However, the amendment has no effect on suits brought in federal court against a state by another state[24] or by the United States.[25] It does not bar suits against local government entities, such as local school boards or educational agencies.[26] Further, it does not bar suits against state officials sued in their individual capacities for illegal activities.[27]

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21. U.S. CONST. amend. XI. The eleventh amendment was proposed and adopted in response to the four to one Supreme Court decision in Chisholm v. Georgia, 2 U.S. (2 Dall.) 419 (1793), which held that a federal court had jurisdiction to hear a suit brought by a South Carolina citizen to collect a Revolutionary War debt from Georgia. *See* Jacobs, *The Eleventh Amendment and Sovereign Immunity* 64-65 (1972). Within two days, Congress proposed constitutional amendments, one virtually identical to the present eleventh amendment. By early 1794, both Houses of Congress had passed the resolution for the eleventh amendment, the Senate by a vote of twenty-three to two, the House by a vote of eighty-one to nine. *See* Nowak, *The Scope of Congressional Power to Create Causes of Action Against State Governments and History of the Eleventh and Fourteenth Amendments*, 75 COLUM. L. REV. 1413, 1436-37 (1975).

22. *Atascadero*, 473 U.S. at 243 (*quoting* Pennhurst State School & Hosp. v. Halderman, 465 U.S. 89, 98 (1984)). *See* Nowak, *supra* note 21. Nowak's argument, which is consistent with the Supreme Court's interpretation of the amendment's significance, is that the amendment is directed not at Congress, but at the federal judiciary. It limits judicial assumption of jurisdiction in suits against states, but does not affect Congress' authority to allow suits by citizens against state defendants when acting pursuant to a constitutional exercise of its powers. Nowak, *supra* note 21, at 1441-45. *See* Note, *The Eleventh Amendment and State Damage Liability Under the Rehabilitation Act of 1973*, 71 VA. L. REV. 655, 658 (1985).

23. Nowak, *supra* note 21, at 1414.

24. *See, e.g.*, North Dakota v. Minnesota, 263 U.S. 365, 372-73 (1923).

25. *See, e.g.*, United States v. Mississippi, 380 U.S. 128, 140-41 (1965), *remanded*, 256 F. Supp. 344 (S.D. Miss. 1966).

26. *See, e.g.*, Lincoln County v. Luning, 133 U.S. 529 (1890); Gary A. v. New Trier High School Dist. No. 203, 796 F.2d 940, 944-47 (7th Cir. 1986).

27. *Ex parte* Young, 209 U.S. 123 (1908). This exception does not apply to suits for damages where state government is the real party in interest. Ford Motor Co. v. Department of Treasury, 323 U.S. 459 (1945): "[W]hen the action is in essence one for the recovery of money from the state, the state is the real, substantial party in interest and is entitled to invoke its sovereign immunity from suit even though individual officials are nominal defendants." *Id.* at 464. *See* Edelman v. Jordan, 415 U.S. 651, 667-69 (1974), *reh'g denied*, 416 U.S. 1000, *rem'd sub nom.* Joran v. Trainer, 405 F. Supp. 802 (N.D. Ill. 1975) (the Court held that even "equitable restitution" is barred if not essential to the injunctive relief).

However, the amendment does serve as a very real constraint on the federal courts, especially as interpreted by a line of restrictive Supreme Court decisions, and has become a strict barrier to suits for money damages not expressly authorized by Congress.[28] In addition, the Supreme Court has construed the principles of Article III[29] together with the purposes of the eleventh amendment to bar suits in federal court brought against a state by citizens of that state, even though the express language of the eleventh amendment does not bar such suits.[30]

B. The Atascadero *Decision*

Although the scope of the eleventh amendment literally extends to any suit in law or equity in federal court, there are two well-established exceptions to the amendment's reach.[31] First, if a state waives its immunity and consents to suit in federal court, the amendment does not bar the action.[32] Secondly, the eleventh amendment is limited by Congress' power under section 5 of the fourteenth amendment to enforce by appropriate legislation the substantive provisions of the fourteenth amendment.[33] The Supreme Court in *Atascadero* addressed the question of whether a suit under the Rehabilitation Act fell within the eleventh amendment bar to suit in federal court by litigants seeking retroactive monetary relief against states and state agencies.[34]

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28. *See* Nowak, *supra* note 21, at 1414.

29. Article III in relevant part, reads:

> The judicial power shall extend to all cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made, or which shall be made, under their Authority; - to all cases affecting Ambassadors, other public Ministers and Consuls; - to all Cases of admiralty and maritime Jurisdiction, - to Controversies between two or more States; - between a State and Citizens of another State; - between Citizens of different States; - between Citizens of the same State claiming Lands under Grants of different State, or the Citizens thereof, and foreign States, Citizens or Subjects.

U.S. CONST. art. III, § 2.

30. Hans v. Louisiana, 134 U.S. 1 (1890). *See infra* note 53.

31. *See* Atascadero State Hosp. v. Scanlon, 473 U.S. 234, 238 (1985).

32. *Id.* (citing Clark v. Barnard, 108 U.S. 436, 447 (1883)).

33. *Id.* (quoting Fitzpatrick v. Bitzer, 427 U.S. 445, 456 (1976)). U.S. CONST. amend. XIV, provides, in part:

> Section 1 . . . No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.
> . . .
> Section 5. The Congress shall have power to enforce, by appropriate legislation, the provisions of this article.

34. *Atascadero*, 473 U.S. at 237. More recent Supreme Court decisions have addressed the eleventh amendment question in varying contexts and the majority opinions in these

The plaintiff in *Atascadero* brought suit under Section 504 of the Rehabilitation Act of 1973 to recover compensatory, injunctive, and declaratory relief against Atascadero State Hospital and the California Department of Mental Health for their refusal to hire him as a graduate student assistant.[35] The Ninth Circuit reversed the district court and held that the eleventh amendment did not bar plaintiff's suit against the state, because the state had participated in Rehabilitation Act programs and therefore had "implicitly consented to be sued as a recipient [of federal assistance] under [section 504]."[36] The Supreme Court in a five to four decision, reversed the Ninth Circuit.[37]

The Supreme Court first addressed the issue of whether California had waived its eleventh amendment immunity to suit in federal court.[38] The Court here reaffirmed its position that a State's general waiver of sovereign immunity in its constitution subjects it to suit in state court, but is not enough to waive the immunity guaranteed by the eleventh amendment.[39] The Court summed up its holding as follows, "[I]n order for a state statutory or constitutional provision to constitute a waiver of eleventh amendment immunity, it must specify the State's intention to subject itself to suit in *federal court*."[40] The Court concluded that the California constitutional provision in question did not specifically indicate such an intention.[41]

Having thus disposed of the issue of whether California had waived its eleventh amendment immunity, the Court in *Atascadero* considered

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cases have followed the stringent standard of "express waiver-abrogation" established in *Atascadero*. *See, e.g.*, Welch v. State Dep't of Highways & Public Transp., 107 S. Ct. 2941 (1987); Papasan v. Allain, 106 S. Ct. 2932 (1986); Green v. Mansour, 474 U.S. 64 (1985). The *Atascadero* decision has been chosen as the focus of this Note both because it established the more stringent standard of "express waiver-abrogation" and because of the similarities between the Rehabilitation Act and the EHA.

35. *Atascadero*, 473 U.S. at 236. Plaintiff suffered from diabetes mellitus and had no sight in one eye, therefore qualifying him as a handicapped individual under the Rehabilitation Act.

36. Scanlon v. Atascadero State Hosp., 735 F.2d 359, 362 (9th Cir. 1984). The court determined on the basis of Edelman v. Jordan, 415 U.S. 651, 671 (1974), that the "threshold fact of congressional authorization to sue a class of defendants which literally includes the States" was present in *Scanlon*. *Atascadero*, 473 U.S. at 237 (quoting *Scanlon*, 735 F.2d at 361).

37. *Atascadero*, 473 U.S. at 237.

38. *Id.* at 241.

39. *Id.* *See* Florida Dep't of Health & Rehab. Servs. v. Florida Nursing Home Ass'n, 450 U.S. 147, 150 (1981) (*per curiam*). The California constitutional provision at issue in *Atascadero* stated: "Suits may be brought against the State in such manner and in such courts as shall be directed by law." CAL. CONST. art. III, § 5.

40. *Atascadero*, 473 U.S. at 241 (emphasis in original).

41. *Id.*

whether Congress abrogated the state's immunity through its enactment of the Rehabilitation Act.[42] The Court, in resolving this issue, looked only to the general statutory language and declined to rely on the Act's statutory inferences or its legislative history to find a congressional intent to abrogate.[43] Instead, the Court concluded that Congress must express its intention to abrogate a state's eleventh amendment immunity from suit "in unmistakable language in the statute itself."[44]

The majority based its reasoning on the need to maintain the "constitutionally mandated balance of power" between state and federal governments.[45] The Court reasoned as follows:

> By guaranteeing the sovereign immunity of the States against suit in federal court, the eleventh amendment serves to maintain this balance. "Our reluctance to infer that a State's immunity from suit in the federal courts has been negated stems from recognition of the vital role of the doctrine of sovereign immunity in our federal system."[46]

While the majority recognized that Congress may provide for private suits against states or state officials in federal court for the purpose of enforcing the provisions of the fourteenth amendment, the Court stated that it would recognize such suits only upon the clearest indication that Congress intended to expand the federal courts' jurisdiction by abrogating eleventh amendment immunity.[47] The Court found such clear indication was absent in the language of the Rehabilitation Act, even though the state was a "recipient of federal assistance" under section 505 of the statute.[48] The Court distinguished the "several states" from other recipients of federal aid because of their constitutional role in maintaining the constitutional balance of power. The Court stated that Congress must specifically subject states to federal jurisdiction in order to abrogate the eleventh amendment.[49]

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42. *Id.* at 242.

43. *Id.* The "general statutory language" referred to by the Court is found at Section 505(a) of the Rehabilitation Act, which describes available remedies as follows:

> The remedies, procedures, and rights set forth in title VI of the Civil Rights Act of 1964 [42 U.S.C. §§ 2000d to 2000d-6] shall be available to any person aggrieved by any act or failure to act by any recipient of Federal assistance or Federal provider of such assistance under section 794 of this title.

29 U.S.C. § 794a(a)(2) (1982 & Supp. 1985).

44. *Atascadero*, 473 U.S. at 243.

45. *Id.* at 242.

46. *Id.* (quoting Pennhurst State School & Hosp. v. Halderman, 465 U.S. 89, 99 (1984)).

47. *Id.* at 243.

48. *Id.* at 245-46. *See supra* note 43 for Section 505's statutory language.

49. *Atascadero*, 473 U.S. at 246 (citing *Pennhurst*, 465 U.S. at 99; Quern v. Jordan, 440 U.S. 332, 342 (1979)).

Finally, the *Atascadero* Court considered whether California had consented to suit in federal court by its acceptance of federal funds under the Rehabilitation Act, an act which authorizes suits against a general class of defendants which literally includes state or state agencies.[50] The Court concluded that although the Ninth Circuit had properly recognized that mere receipt of federal funds cannot establish a state's consent to suit in federal court, the Ninth Circuit had erred in deciding that a state consents to suit in federal court by participating in programs under the Rehabilitation Act.[51] Just as the Court decided that the Rehabilitation Act did not demonstrate an unmistakable congressional intent to abrogate a state's eleventh amendment immunity in federal court, the Court likewise found that the Rehabilitation Act "fell far short" of indicating a congressional intent to condition participation in the Act's programs on a state's waiver of its constitutional immunity.[52] Thus, the states won a major victory by expanding the scope of their immunity from suit in federal court through the "express waiver-abrogation" requirements established in *Atascadero*.

Four justices disagreed. Justices Brennan, Marshall, Blackmun and Stevens believed the majority had once again followed the "misguided history" of the eleventh amendment to exempt "the States from compliance with laws that bind every other legal actor in our Nation."[53]

Justice Brennan, writing for the dissent, did not attack state waiver of immunity; however, Justice Brennan did object to the majority's "stringent" test in this regard.[54]

> The "stringent" . . . test that the Court applies to purported state waivers of sovereign immunity is a mirror image of the

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50. *Id.* at 246.

51. *Id.* at 246-47. The Ninth Circuit was relying on the language of Edelman v. Jordan, 415 U.S. 651, 672 (1974), that authorization of such a class would be sufficient to abrogate. The Court in *Edelman* found such a congressional authorization to sue a class of defendants which literally included the states, however, was wholly absent in the statute enacting the Aid to the Aged, Blind and Disabled Program.

52. *Atascadero*, at 247. The Court further noted:

> Thus were we to view this statute as an enactment pursuant to the Spending Clause, Art. I, § 8 . . . we would hold that there was no indication that the State of California consented to federal jurisdiction.

Id. See infra text accompanying note 76.

53. *Id.* at 248. The Brennan dissent contains an exhaustive historical analysis of the eleventh amendment which is beyond the scope of this Note to discuss in detail. *See id.* at 247-302. However, the basic premise of his dissent is on the ground that Hans v. Louisiana, 134 U.S. 1 (1890), was erroneously decided, as the eleventh amendment was not enacted to bar suits by citizens against their own state based upon federal question jurisdiction. *See id.* at 260.

54. *Atascadero*, 473 U.S. at 253 n.5.

> test it applies to congressional abrogation of state sovereign immunity. Just as the Court today decides that Congress, if it desires effectively to abrogate a State's sovereign immunity, must do so expressly in the statutory language, so the Court similarly decides that a State's waiver, to be effective, must be "specifically applicable to federal court jurisdiction."[55]

Therefore, the majority, in the eyes of the dissent, imposed the same special rules of statutory draftsmanship on state legislatures as it did on Congress before immunity to suit in federal court could effectively be waived, instead of properly construing a state constitution in accordance with its own legislative history and state law.[56]

The dissent then examined the statutory language and purpose of the Rehabilitation Act and found it "quite incredible" that Congress would intend that states be exempt from liability for discrimination under the Rehabilitation Act, while at the same time receiving a large percentage of the Act's federal funds.[57] The dissent pointed to other instances in which the statutory language "recipient of federal assistance" had led federal agencies to promulgate regulations which specifically defined states and state agencies as recipients of federal assistance, and emphasized that the Rehabilitation Act's wording had been patterned after such statutes.[58] The dissent found that the Rehabilitation Act expressly stated in section 505 that its remedies against "any act or failure to act by any recipient of Federal assistance," included the remedies found in Title VI of the Civil Rights Act of 1964, one of the statutes which specifically defines state and state agencies as recipients.[59] The dissent concluded from these

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55. *Id.*

56. *Id.* If this reading of the majority opinion is correct, then arguably the Court has dispensed with the rule that a state waiver of immunity may result because of "overwhelming implications from the text," which was the test used in Florida Dep't of Health & Rehab. Servs. v. Florida Nursing Home Ass'n, 450 U.S. 147, 150 (1981) (per curiam) and Edelman v. Jordan, 415 U.S. 651, 673 (1974).

57. *Atascadero*, 473 U.S. at 248-49.

58. *Id.* at 249-50. Soon after Title VI of the Civil Rights Act of 1964, codified at 42 U.S.C. § 2000d (1982 & Supp. 1985), was enacted, which bans discrimination of the basis of race, color, or national origin by "any program or activity receiving Federal financial assistance," seven agencies promulgated regulations defining states as recipients of federal financial assistance. Another statute which uses Title VI's definition of "recipient" is Title IX of the Education Amendments of 1972, which prohibits discrimination on the basis of sex by "any education program or activity receiving Federal financial assistance." 20 U.S.C. § 1681(a) (1982).

59. *Atascadero*, 473 U.S. at 252. *See supra* language of Section 505. Representative Jeffords stated upon the enactment of Section 505 that "it did not seem right to me that the Federal Government should require States and Localities to eliminate discrimination against the handicapped wherever it exists and remain exempt themselves." 124 Cong. Rec. 38, 551 (1978). *See Atascadero*, 473 U.S. at 251 n.4.

factors that Congress clearly intended to subject states under the Rehabilitation Act to both a duty not to discriminate against the handicapped and an amenability to all the remedies available against other entities as a "recipient of Federal assistance."[60]

The dissent further attacked the majority opinion on the ground that the Court's "series of special rules of statutory draftsmanship" used to abrogate eleventh amendment immunity, were not justified as efforts to determine congressional intent.[61] The dissent argued that these rules, instead of determining the intent of Congress, were instead being used by the Court to ignore the will of Congress and to deny damage awards which might be a plaintiff's only practical remedy, on a flawed constitutional policy of disfavoring suits against states by their own citizens.[62]

C. State Waiver of Immunity

The *Atascadero* opinion discussed two ways in which a state could waive its eleventh amendment immunity: through enactment of a state statute or constitutional provision which specifies an intention to subject the state to suit in federal court[63] and through a state's participation in programs which condition participation on a state's waiver of constitutional immunity.[64] In addressing the first way to waive immunity, the *Atascadero* majority did not go so far as to hold that the constitutional or statutory provision must expressly state that "the state waives its immunity to suit in federal court." However, it could reasonably be inferred that these words or their equivalent are now necessary to waive immunity, as California did have a constitutional provision waiving its sovereign immunity.[65]

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60. *Atascadero*, 473 U.S. at 252.

61. *Id.* at 252-55. Employees v. Department of Public Health & Welfare, 411 U.S. 279 (1973), held that Congress must make its intention "clear" to lift a state's immunity. Edelman v. Jordan, 415 U.S. 651, 673 (1974) (citing Murray v. Wilson Distilling Co., 213 U.S. 151, 171 (1909)), held "we will find waiver only where stated by the most express language or 'by such overwhelming implications from the text as [will] leave no room for any other reasonable construction.'" Pennhurst State School & Hosp. v. Halderman, 465 U.S. 89, 99 (1984) required "an unequivocal expression of congressional intent." Brennan felt *Atascadero* "tightens the noose" by requiring that Congress must express that unequivocal intention *in the statute itself* and thus changed the rules of lawmaking Congress was acting under when it enacted Section 504. 473 U.S. at 254 & n.7.

62. *Atascadero*, 473 U.S. at 254-55. Congress, in response to the *Atascadero* decision, amended the Rehabilitation Act to clearly provide for private suits for money damages against a State. *See infra* notes 193-96 and accompanying text.

63. *See supra* notes 38-40 and accompanying text.

64. *See supra* notes 50-52 and accompanying text.

65. *See* McClintock, *The* Atascadero *Rule: New Hurdle for Plaintiffs Suing States in Federal Court*, 21 GONZAGA L. REV. 47, 70 (1985/86).

One nationwide review that has been done of state constitutional and statutory provisions indicated that state would meet this "stringent" test if that is the interpretation to be placed on *Atascadero*.[66] Some states, including Florida, Maine, Mississippi, Nevada, Oklahoma and Pennsylvania, have expressly preserved their immunity from suit in federal court.[67] Other states, such as Idaho, Utah and Georgia, indicate that the state is not to be made a defendant in federal court.[68] A number of states, including California, do have provisions waiving sovereign immunity, while others, such as New York, Michigan and Indiana, have no sovereign immunity provisions.[69] No state waiver provisions, however, mention the eleventh amendment or federal courts expressly.[70]

The waiver of a state's immunity through its participation in federal programs and receipt of these programs' benefits had earlier been recognized by the Supreme Court in *Parden v. Terminal Railway*.[71] In *Parden*, a majority of the Court held that although nothing in the Federal Employer's Liability Act's (FELA)[72] language or statutory history indicated an intent to abrogate state immunity, the state was liable for damages in a personal injury suit brought under the Act, because Congress intended to subject states which operated railways to liability under FELA.[73] Justice Brennan in the majority opinion emphasized that, "[b]y empowering Congress to regulate commerce . . . the States necessarily surrendered any portion of their sovereignty that would stand in the way of such regulation."[74] The *Parden* decision thus recognized that actual waiver by the states is not necessary to lift the bar on a state's immunity as Congress is empowered to lift the bar for them in circumstances where Congress is exercising power expressly granted to it in Article I.[75]

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66. *Id.* at 71-73.

67. *Id.* at 71. *See* FLA. STAT. ANN. § 768.28(16) (West Supp. 1989); ME. REV. STAT. ANN. tit. 14, § 8118 (1980); MISS. CODE ANN. § 11-46-5(4) (Supp. 1988); NEV. REV. STAT. § 41.031(3) (1979); OKLA. STAT. ANN. tit. 51, § 152.1(B) (West 1988); PA. STAT. ANN. tit. 42, § 8521(b) (Purdon 1982).

68. McClintock, *supra* note 65, at 71. *See* IDAHO CODE § 6-903(f) (Supp. 1987); UTAH CODE ANN. § 63-30-4 (1986); GA. CONST. art. I, § 2, § 9(a).

69. McClintock, *supra* note 65, at 72. *See* Trotman v. Palisades Interstate Park Comm., 557 F.2d 35 (2d Cir. 1977); Dawkins v. Craig, 483 F.2d 1191 (4th Cir. 1973); Stanley v. Indiana Civil Rights Comm'n, 557 F. Supp. 330 (N.D. Ind. 1983), *aff'd*, 740 F.2d 972 (7th Cir. 1984).

70. McClintock, *supra* note 65, at 72. *See supra* notes 38-40 and accompanying text.

71. 377 U.S. 184 (1964).

72. 45 U.S.C. § 51 (1982).

73. Parden v. Terminal Ry. of Alabama State Docks Dep't, 377 U.S. 184, 190 (1964). *See* Nowak, *supra* note 21, at 1416 n.15.

74. *Parden*, 377 U.S. at 192.

75. Nowak believed the *Parden* decision was subject to at least three different

The *Atascadero* decision, however, held that the state's receipt of funds under the Rehabilitation Act did not abrogate the state's immunity to suit in federal court as an enactment pursuant to the Spending Clause in Article I.[76] The Court stated for a waiver to be found, there must be a clear congressional intent to condition participation in the federal programs on a state's consent to waive its constitutional immunity.[77] The *Atascadero* court thus implied that this congressional intent could only be found in the regulatory statute's language, not in the general purpose of a statute to make the states recipients of its benefits.

This implied holding in *Atascadero* was made express by the Supreme Court's subsequent decision in *Welch v. Texas Department of Highways and Public Transportation*.[78] Although the issue of a state's waiver of immunity was not directly before the Court in *Welch*,[79] the Court took the opportunity to overrule *Parden* to the extent that it is inconsistent with the requirement that abrogation by Congress be stated in unmistakably clear language in the statute itself.[80] The Court noted that the majority in *Parden* had mistakenly reasoned that general language in FELA made the statute applicable to states, as they received benefits under the Act.[81] The Court in *Welch* instead agreed with the dissenting opinion in *Parden* which stated:

> It should not be easily inferred that Congress, in legislating pursuant to one article of the Constitution, intended to effect

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interpretations. First, Congress can create federal damage actions against states under its powers as long as the regulated activity is within the scope of those powers also. Second, Congress can establish federal damage actions against states and the Court should interpret the statutes as creating such causes of action whenever the states come within the class of persons subject to such suits. Third, Congress can regulate the activity and force states to elect between consenting to federal jurisdiction in damage suits or discontinuing the regulated activity. Nowak, *supra* note 21, at 1417.

76. *See supra* note 52 and accompanying text.

77. *Atascadero*, 473 U.S. at 247.

78. 107 S. Ct. 2941 (1987). Decisions prior to *Atascadero* had already begun to question the Court's decision in *Parden*. *See, e.g.*, Employees v. Department of Public Health & Welfare, 411 U.S. 279 (1973) (Supreme Court, although it recognized Congress' power to lift a State's immunity, refused to find such abrogation under the Fair Labor Standards Act as there was no clear statement of such a congressional intent, and the Fair Labor Standards Act involved a traditional governmental function as opposed to the proprietary function found in *Parden*); Edelman v. Jordan, 415 U.S. 651 (1974) (in a case brought under the Aid to the Aged, Blind and Disabled program, the Court questioned in dicta the *Parden* theory that a state may impliedly consent to suit merely by participating in a federally regulated or funded activity).

79. *See* Welch v. Texas Dep't of Highways & Public Transp., 107 S. Ct. 2941, 2946-47 (1987).

80. *Id.* at 2947-48.

81. *Id. See Parden*, 377 U.S. at 190.

> an automatic and compulsory waiver of rights arising under another. Only when Congress has clearly considered the problem and expressly declared that any State which undertakes given regulable conduct will be deemed thereby to have waived its immunity should courts disallow the invocation of this defense.[82]

Therefore, negating eleventh amendment immunity can be accomplished by the states in either their constitutions or legislation, or by Congress in federal statutes. Whatever the method, however, *Atascadero*'s test requires, on the face of the statute or constitution itself, express abrogating language or unmistakably clear intent for states to be sued in federal court; a waiver will no longer be implied from a statute's general purposes.

D. Congressional Abrogation Under Its Fourteenth Amendment Powers

An analysis of congressional abrogation of immunity under the fourteenth amendment should begin with *Fitzpatrick v. Bitzer*,[83] which addressed the issue of whether "Congress has the power to authorize federal courts to enter (a monetary damage) award against the State as a means of enforcing the substantive guarantees of the Fourteenth Amendment."[84] *Fitzpatrick* involved a class action on behalf of Connecticut's male state employees, which alleged that the State's retirement plan discriminated against them because of their sex, and therefore was in violation of Title VII of the Civil Rights Act of 1964.[85]

The district court found the retirement plan was discriminatory and entered prospective injunctive relief against the state in favor of the plaintiffs; however, the district court refused to allow recovery of money damages against the state on the ground they were barred by the eleventh amendment.[86] The appellate court affirmed the district court, holding that *Edelman v. Jordan*[87] mandated that "'a private federal action for retroactive damages' is not a 'constitutionally permissible method of enforcing fourteenth amendment rights.'"[88]

The Supreme Court began its analysis in *Fitzpatrick* with the recognition that Title VII expressly authorized suits against the state as an

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82. *Welch*, at 2948 (quoting *Parden*, 377 U.S. at 198-99 (White, J., dissenting)).

83. 427 U.S. 445 (1976).

84. *Id.* at 448. *See* U.S. CONST. amend. XIV, *supra* note 33.

85. *Fitzpatrick*, 427 U.S. at 448. Title VII, as amended, is codified at 42 U.S.C. §§ 2000e to 2000e-17 (1982).

86. *Fitzpatrick*, 427 U.S. at 449-50.

87. 415 U.S. 651 (1974).

88. *Fitzpatrick*, 427 U.S. at 450-51 (quoting Fitzpatrick v. Bitzer, 519 F.2d 559, 569 (2d Cir. 1975)).

employer, pursuant to congressional authority under Section 5 of the fourteenth amendment, to enforce, by appropriate legislation, the prohibitions, guaranteed rights and immunities of the fourteenth amendment.[89] The Court then addressed the relationship between the Section 5 enforcement provision and the substantive provisions of the fourteenth amendment. It quoted at length from the earlier Supreme Court decision in *Ex parte Virginia*,[90] a case in which a state judge had been indicted under a federal statute prohibiting the exclusion, on the basis of race, of a citizen from service as a juror in state court. The Court in *Ex parte Virginia* held that:

> The prohibitions of the fourteenth amendment are directed to the States, and they are to a degree restrictions of State Power. It is these which Congress is empowered to enforce, and to enforce against State action, however put forth, whether that action be executive, legislative or judicial. Such enforcement is no invasion of State sovereignty. No law can be, which the people of the States have, by the Constitution of the United States, empowered Congress to enact. . . .
>
> [I]n exercising her rights, a State cannot disregard the limitations which the Federal Constitution has applied to her power. Her rights do not reach to that extent. Nor can she deny to the general government the right to exercise all its granted powers, though they may interfere with the full enjoyment of rights she would have if those powers had not thus been granted. Indeed, every addition of power to the general government involves a corresponding diminution of the governmental powers of the States. It is carved out of them. . . .
>
> Were it not for the fifth section of [the Fourteenth] Amendment, there might be room for argument that the first section is only declaratory of the moral duty of the State . . . . But the Constitution now expressly gives authority for congressional interference and compulsion in the cases embraced within the fourteenth amendment. It is but a limited authority, true, extending only to a single class of cases; but within its limits it is complete.[91]

Ex Parte Virginia interpreted the fourteenth amendment as a prohibition, meaning that no state agency or state official shall deny to any person within that state the equal protection of the laws.[92]

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89. *Id.* at 452-53.
90. 100 U.S. 339 (1879).
91. *Id.* at 346-48.
92. *Id.* at 347.

Because the fourteenth amendment inherently limits state sovereignty, the *Fitzpatrick* Court concluded that Congress had the authority, for the purpose of enforcing the substantive provisions of the fourteenth amendment, to "provide for private suits [for money damages] against States and State officials which are constitutionally impermissible in other contexts [under the eleventh amendment]."[93] The *Fitzpatrick* Court recognized two crucial interpretations of the fourteenth amendment: first, that the substantive provisions of the fourteenth amendment are directed at the states and through those provisions the states have duties with respect to the treatment of private individuals; and secondly, because these constitutional duties are to be enforced in federal court, there should be a third way in which a state's eleventh amendment immunity can be abrogated.[94] In the fourteenth amendment context, the Court in *Fitzpatrick* held that state consent to suit in federal court is unnecessary as the states have already waived their immunity in part through ratification of the fourteenth amendment.[95]

Prior to *Atascadero*, the sufficiency of the statutory language to effectively abrogate immunity had not been considered in a fourteenth amendment context.[96] In light of *Atascadero*, however, it is doubtful that an implied waiver of immunity through ratification of the fourteenth amendment will be enough in these suits to override the eleventh amendment bar to suit in federal court. Although the court will still recognize implied waivers of state immunity under Section 5 of the fourteenth amendment, *Atascadero* appears to hold that the statute in question must also meet the "unmistakably clear language in the statute itself" test prior to abrogating a state's immunity.

III. The Eleventh Amendment and the Education for All Handicapped Children Act of 1975

A. Availability of Monetary Relief Under the EHA

The EHA provides aggrieved parties with a private right of action for relief pursuant to the procedural safeguards in section 1415 of the Act.[97] However, there has been continuing debate concerning whether retroactive monetary relief is available at all under the EHA, and if so,

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93. *Fitzpatrick*, 427 U.S. at 456.

94. *Id.* at 457-58. *See also* Atascadero State Hosp. v. Scanlon, 473 U.S. 234, 238 (1985); McClintock, *supra* note 65, at 58-59.

95. *Fitzpatrick*, 427 U.S. at 453.

96. *See Fitzpatrick*, 427 U.S. 445; McClintock, *supra* note 65, at 70.

97. 20 U.S.C. § 1415 (1982). *See* Gary A. v. New Trier High School Dist. No. 203, 796 F.2d 940, 944 (7th Cir. 1986); Mountain View-Los Altos Union High School Dist. v. Sharron B.H., 709 F.2d 28, 29 (9th Cir. 1983).

what types of relief should be included in this category.[98] Therefore, a discussion of this broader debate is necessary prior to an analysis of the eleventh amendment bar to retroactive monetary relief under the Act.

The debate over the availability of retroactive monetary relief under the EHA centers on the meaning to be given the term "appropriate" as it is used in connection with relief to be granted under the Act.[99] Prior to 1985, some courts refused to hold that any form of monetary relief was available under the Act, or was available only under exceptional circumstances,[100] while other courts allowed retroactive monetary relief as the only remedy which could effectively redress violations of the Act.[101]

The prevailing standard for an award of monetary relief under the EHA during that time was expressed in *Anderson v. Thompson*.[102] The court there held that "Congress did not envision appropriate relief [under the EHA] generally to include a damage remedy. Instead, section [1415(e)(2)] appears to be the last of many procedural safeguards in a section aimed at ensuring proper placements and programs for handicapped children."[103] The court in *Anderson* took judicial notice of the developing status of the field of special education, and based its decision in part on its belief that handicapped educational programs would suffer if school officials and educational agencies feared monetary liability.[104] The decision in *Anderson*, however, was not absolute. The court recognized two exceptions to the general unavailability of damages under the Act: where a child's physical health would be endangered by the individualized educational program and where the defendant had acted in bad faith by his failure to comply with the procedural safeguards of the Act.[105]

The rule in *Anderson* was generally held by other courts to apply to all types of monetary relief, including tuition reimbursements for inappropriate educational placements, until the Supreme Court decision in *Burlington School Committee v. Department of Education*.[106] The

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98. *See supra* note 12 and accompanying text.

99. 20 U.S.C. § 1415(e)(2) (1982). *See supra* note 11.

100. *See, e.g.*, Colin K. v. Schmidt, 715 F.2d 1, 10 (1st Cir. 1983); Marvin H. v. Austin Indep. School Dist., 714 F.2d 1348, 1356 (5th Cir. 1983); Powell v. Defore, 699 F.2d 1078, 1081 (11th Cir. 1983); Miener v. Missouri, 673 F.2d 969, 979 (8th Cir. 1982); Anderson v. Thompson, 658 F.2d 1205, 1209-10 (7th Cir. 1981); Sanders v. Marquette Pub. Schools, 561 F. Supp. 1361, 1366 (W.D. Mich., N.D. 1983).

101. *See, e.g.*, Hurry v. Jones, 734 F.2d 879, 883 (1st Cir. 1984); Department of Educ., Hawaii v. Katherine D., 727 F.2d 809, 817 (9th Cir. 1983), *cert. denied*, 471 U.S. 1117 (1985).

102. 658 F.2d 1205 (7th Cir. 1981).

103. *Id.* at 1211.

104. *Id.* at 1213.

105. *Id.* at 1213-14.

106. 471 U.S. 359 (1985). *See, e.g.*, Marvin H. v. Austin Indep. School Dist., 714

Anderson rule for awarding monetary relief had been increasingly criticized by the circuits, particularly in the area of tuition reimbursements for inappropriate programs.[107] The Supreme Court resolved this issue by taking retroactive reimbursements out of the context of damages and finding them available as relief under the Act.[108]

In reaching its conclusion, the Court looked to the procedural safeguards found in the EHA. The Court discovered these safeguards included the right of parents to participate in the development of an individualized educational program (IEP), as well as the right for the child to challenge a program with which he disagrees in administrative and court proceedings.[109] The Court recognized that:

> Where as in the present case review of a contested IEP takes years to run its course—years critical to the child's development—important practical questions arise concerning interim placements of the child and financial responsibility for that placement.[110]

Prospective injunctive relief as a sole remedy was found to be inadequate by the Court, as parents who disagreed with a proposed IEP would then have only two choices: go along with the inappropriate IEP to the detriment of their child, or pay for what is determined later to be an appropriate placement.[111]

> If [prospective injunctive relief was the sole remedy], the parents' right to a *free* appropriate public education, the parents' right to participate fully in developing a proper IEP, and all of the procedural safeguards would be less than complete. Because Congress undoubtedly did not intend this result, we are confident that by empowering the court to grant "appropriate" relief Congress meant to include retroactive reimbursement to parents as an available remedy. . . . Reimbursement merely requires the [Burlington School Committee] to belatedly pay expenses that it should have paid all along and would have borne in the first instance had it developed a proper IEP.[112]

F.2d at 1354 (included tuition reimbursement as a type of damages); Mountain View-Los Altos Union High School Dist. v. Sharron B.H., 709 F.2d at 30 (same); Parker v. District of Columbia, 588 F. Supp. 518, 521 (D.D.C. 1983) (same).

107. *See, e.g., Department of Educ., Hawaii*, 727 F.2d at 816-18; Doe v. Brookline School Comm., 722 F.2d 910 (1st Cir. 1983).

108. *Burlington*, 471 U.S. at 370-71.

109. *Id.* at 361. *See* 20 U.S.C. §§ 1401(19), 1415(b), (d), (e) (1982).

110. *Burlington*, 471 U.S. at 361.

111. *Id.* at 370.

112. *Id.* at 370-71 (emphasis in original). *See* 34 C.F.R. § 300.403(b) (1984) (disagreements and questions of financial responsibility subject to *post-hoc* due process procedures).

Burlington thus establishes that at least one form of retroactive monetary relief, although not characterized by the Court as damages, is available under the EHA.

In addition, Congress recently authorized the award of attorney's fees as part of the costs to the parent of a handicapped child who is the prevailing party in a suit brought under the Act.[113] The Handicapped Children's Protection Act (HCPA) of 1986[114] was enacted to allow for both this award of attorney's fees and to "clarify the effect of the [EHA] on rights, procedures, and remedies under other laws relating to the prohibition of discrimination."[115] The HCPA was enacted in response to the 1984 Supreme Court decision in *Smith v. Robinson*.[116] *Smith* held that the EHA was the "exclusive avenue" by which a parent could assert an equal protection claim against a publicly financed educational agency.[117] The Court reached this conclusion through an analysis of the comprehensiveness and detail of the procedural safeguards found in the EHA and through "express congressional efforts to place primary responsibility on local and state educational agencies" for developing appropriate plans and individual educational programs.[118] This decision resulted in lower courts' dismissing equal protection claims brought under section 504 of the Rehabilitation Act and section 1983 of the Civil Rights Act, where the remedy found under the EHA was more clear and precise.[119]

Congress acted to correct this mistaken interpretation of their intent by explicitly amending the EHA to include awards of attorney's fees, as well as expressly allowing actions to be brought under both the EHA and other laws which protect the rights of handicapped children.[120] In

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113. 20 U.S.C.A. § 1415(e)(4)(B) (West Supp. 1988). This section provides:

> In any action or proceeding brought under this subsection, the court, in its discretion, may award reasonable attorney's fees as part of the costs to the parents or guardian of a handicapped child or youth who is the prevailing party.

114. Pub. L. No. 99-372, 100 Stat. 796 (1986).

115. S. REP. No. 112, 99th Cong., 2d Sess. 1, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS 1798, 1798 [hereinafter S. REP. No. 112].

116. 468 U.S. 992 (1984). *See* S. REP. No. 112 *supra* note 115, at 2.

117. 468 U.S. at 1009.

118. *Id.* at 1009-11.

119. *See, e.g.*, Miener v. Missouri, 800 F.2d 749, 754-55 (8th Cir. 1986); Alexopulos v. Riles, 784 F.2d 1408, 1410 (9th Cir. 1986).

120. 20 U.S.C.A. § 1415(f) (West Supp. 1988) provides:

> Nothing in this chapter shall be construed to restrict or limit the rights, procedures, and remedies available under the Constitution, title V of the Rehabilitation Act of 1973, or other Federal statutes protecting the rights of handicapped children and youth, except that before the filing of a civil action under such laws seeking relief that is also available under this subchapter, the procedures under subsections (b)(2) and (c) of this section shall be exhausted to the same extent as would be required had the action been brought under this subchapter.

the legislative history of the HCPA, it is clear that Congress intended states to be responsible for attorneys fees in appropriate cases.[121] Based on the foregoing, attorneys' fees, as well as retroactive tuition reimbursement, are clearly included as types of monetary relief now available under the EHA.

It is still unsettled whether money damages, apart from tuition reimbursements, are available under the EHA. Some courts have concluded that while the *Anderson v. Thompson* test is overruled as to the availability of tuition reimbursement, it is still viable on the broader question of availability of damages under the EHA.[122] Therefore, money damages could be awarded under the *Anderson* test in cases where: (1) an IEP endangers the life of a child; or (2) there has been a bad faith failure to comply with the procedural safeguards of the EHA.[123]

B. Abrogation of State Immunity from Suit in Federal Court Under the EHA

Since *Atascadero*, four circuits and several district courts have addressed the question of state immunity to suits brought under the EHA. These cases have split on the question of whether the language of the EHA satisfies the "unmistakable language" standard enunciated in *Atascadero*, and illustrate the difficulties of applying what "unmistakable language" really means.

In *Gary A. v. New Trier High School District No. 203*,[124] plaintiffs brought suit under the EHA against various state entities to obtain reimbursement for their child's educational expenses at a private residential facility.[125] The district court rejected the state defendants' eleventh amend-

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121. *See* S. REP. No. 112 *supra* note 115, at 13 (emphasis added):

> The [Senate Labor and Human Resources Committee] understands and intends that *State* and local agencies may not use funds made available to them under Part B of the EHA to pay attorney's fees or other costs incurred by parents that a court assesses against those agencies under the [HCPA]. Using these funds for those costs would divert scarce resources from direct services to handicapped children.

Note further that in 20 U.S.C.A. § 1415(e)(4)(G) (West Supp. 1988), Congress provided that the subsection dealing with reductions of attorney's fee awards would not apply in cases where the *State* or local educational agency unreasonably protracted the litigation.

122. *See, e.g.*, Silano v. Tirozzi, 651 F. Supp. 1021 (D. Conn. 1987); Gerasimou v. Ambach, 636 F. Supp. 1504, 1512 (E.D.N.Y. 1986).

123. *See supra* note 105 and accompanying text.

124. 796 F.2d 940 (7th Cir. 1986) (per curiam). *See also* Tonya K. v. Board of Educ., 847 F.2d 1243 (7th Cir. 1988) (reaffirmed the *Gary A.* decision).

125. *Gary A.*, 796 F.2d at 942. Plaintiffs also brought suit under the equal protection clause of the fourteenth amendment and state law, which claims were rejected by the district court.

ment defense and awarded the plaintiffs the costs of the child's education.[126] The Seventh Circuit reversed the district court, holding that in light of *Atascadero*, the state could not waive its immunity to suit in federal court by mere participation in a federally funded program.[127] Further, the court held that Congress had not effectively abrogated the state's immunity to suit in federal court under the EHA.[128] The court arrived at this conclusion by the bare finding that the EHA "is similar in all relevant parts" to section 504 of the Rehabilitation Act,[129] the statute at issue in *Atascadero*.[130] The court briefly noted three broad similarities between the Rehabilitation Act and the EHA, but refused to go beyond a facial comparison and examine the express statutory language of the EHA and the policy rationales which instigated the legislation's enactment.[131]

This cursory treatment of the EHA contrasts sharply with the Seventh Circuit's treatment of sufficient congressional abrogation only six months later in *Gomez v. Illinois State Board of Education*,[132] a case involving eleventh amendment immunity under the Equal Educational Opportunities Act of 1974 (EEOA).[133] In *Gomez*, the Seventh Circuit engaged in a complete statutory analysis and investigation of the EEOA to determine that its language did indeed abrogate a state's immunity to suit in federal court.[134] Instead of looking at broad similarities between two different statutes as the court did in *Gary A.*,[135] the Seventh Circuit instead looked to the EEOA's intended effect to hold that barring states from immunity to suit would render nugatory express terms of the Act.[136] This disparity in analysis is particularly disturbing because the similarities in language between the EHA and the EEOA are much closer than is the language between the EHA and the Rehabilitation Act.[137]

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126. *Id.*

127. *Id.* at 943. *See supra* notes 50-52 and accompanying text.

128. *Gary A.*, 796 F.2d at 944.

129. 29 U.S.C. § 794 (1982 & Supp. 1985).

130. *Gary A.*, 796 F.2d at 944.

131. *Id.* These broad similarities included: both statutes explicitly provide a private right of action for prospective relief for aggrieved parties; neither statute explicitly provides for retroactive relief; and both involve programs by which states receive federal assistance. *See infra* notes 168-89 and accompanying text.

132. 811 F.2d 1030 (7th Cir. 1987).

133. 20 U.S.C. § 1703(f) (1982).

134. *Gomez*, 811 F.2d at 1037-38. See *infra* notes 168-89 and accompanying text for a statutory construction of the EHA following the example of *Gomez*.

135. 796 F.2d at 940.

136. *Gomez*, 811 F.2d at 1038.

137. *See infra* notes 168-89 and accompanying text.

In another EHA case, *Doe ex rel. Gonzales v. Maher*,[138] the plaintiffs argued on appeal that the district court had erroneously dismissed their damage claims based on the EHA.[139] The Ninth Circuit, however, affirmed the district court on the basis of *Atascadero*.[140] The Ninth Circuit first found that California had not waived its immunity to suit in federal court based on the Supreme Court's holding in *Atascadero* that the California constitution did not specify California's intention to subject itself to suit in federal court.[141] The court then looked to the language of the EHA provision authorizing suits in federal court, and found that the language "simply does not pass muster under the stringent [*Atascadero*] test."[142] Finally, the court found the EHA did not expressly condition the state's right to receive funds on their willingness to waive their sovereign immunity.[143]

The Ninth Circuit, in determining whether a state's immunity to suit in federal court had been abrogated, thus looked at one provision of the EHA, which authorizes citizen suits in federal court, in isolation. Although the *Atascadero* decision imposes an "unmistakable language in the statute itself" standard on federal statutes before immunity will be found to have been abrogated, the opinion did not go so far as to state that this language must be found exclusively in the part of the statute authorizing citizen suits in federal court.[144]

Neither *Gary A.*[145] nor *Doe ex rel. Gonzales v. Maher*[146] came close to a complete statutory analysis of the EHA in arriving at their conclusions. However, the First Circuit in *David D. v. Dartmouth School Committee*,[147] also addressed the issue of whether the EHA effectively

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138. 793 F.2d 1470 (9th Cir. 1986), *aff'd on other grounds sub nom.* Honig v. Doe, 108 S. Ct. 592 (1988).

139. *Id.* at 1493. The major issue in this decision, which was recently addressed by the Supreme Court, was whether the EHA prohibits expulsion of handicapped students for misbehavior that is a manifestation of their handicap. Both the Ninth Circuit and the Supreme Court found such a prohibition.

140. *Id.* In doing so, the Ninth Circuit held that prior Ninth Circuit decisions which had found that California had waived its immunity to suit in federal court, such as: Students of Cal. School for the Blind v. Honig, 736 F.2d 538 (9th Cir. 1984) and Department of Educ. v. Katherine D., 727 F.2d 809 (9th Cir. 1984), no longer carried any force in light of *Atascadero*.

141. *Doe ex rel. Gonzales*, 793 F.2d at 1494. *See supra* notes 38-41 and accompanying text.

142. *Id.* The "language" referred to by the court is found at 20 U.S.C. § 1415(e)(2) (1982).

143. *Id.*

144. *Id. See supra* notes 50-52 and accompanying text.

145. 796 F.2d 940.

146. 793 F.2d 1470. *See* McClintock *supra* note 65, at 53 n.34. "Courts are faced with not only 'if' Congress 'said' abrogation, but 'where.'"

147. 775 F.2d 411 (1st Cir. 1985), *cert. denied*, 475 U.S. 1140 (1986).

abrogated states' immunity from suit in federal court.[148] This case involved an appeal from a district court order using Massachusetts' higher special education standards, to place a seventeen-year old boy with Downs Syndrome in a private residential school.[149] Massachusetts argued on appeal that the district court erred in enforcing state substantive law against it absent a waiver of the state's eleventh amendment immunity to suit in federal court. The appellate court disagreed with Massachusetts' position.[150]

The First Circuit found that the EHA's language, which defines a "free appropriate education" as "special education and related services which . . . meet the standards of the state educational agency,"[151] explicitly incorporated state substantive law into the EHA; therefore, state substantive law could be reviewed by a federal court under its federal question jurisdiction pursuant to the Act, and was not a pendent state law claim which is barred by the eleventh amendment from federal court jurisdiction under *Pennhurst, II*,[152] a 1984 Supreme Court decision.[153] The court concluded such a holding withstood Massachusetts' eleventh amendment challenge even under the more rigorous rules of *Atascadero*.

The First Circuit focused on whether Congress effectively overrode the states' immunity to suit in federal court under the EHA and concluded that it did. The court distinguished the EHA from the statute in issue in *Atascadero*, the Rehabilitation Act, on the ground that in section 1400(b)(9) of the EHA[154] Congress expressly, as opposed to implicitly, declared that it was acting to assure equal protection of the law.[155] Further, the court noted that the Supreme Court had expressly recognized that the EHA was grounded on the equal protection clause of the fourteenth amendment. Section 1400(b)(9) of the EHA states:

> It is in the national interest that the Federal Government assist State and local efforts to provide programs to meet the educational needs of handicapped children in order to assure equal protection of the law.[156]

The court found this to mean state consent to suit is unnecessary under the EHA as a state has already waived a portion of its immunity through

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148. *Id.* at 414.
149. *Id.*
150. *Id.*
151. 20 U.S.C. § 1401(18)(B) (1982).
152. Pennhurst State School & Hosp. v. Halderman, 465 U.S. 89 (1984).
153. *David D.*, 775 F.2d at 417.
154. 20 U.S.C. § 1400(b)(9) (1982).
155. *David D.*, 775 F.2d at 421.
156. 20 U.S.C. § 1400(b)(9) (1982).

ratification of the fourteenth amendment, whereas the Court had made no similar finding regarding the Rehabilitation Act.[157]

Finally, the First Circuit distinguished the EHA from the Rehabilitation Act on the basis of its remedies.

> Unlike the remedies for violation of § 504 of the RHA, which are broadly directed by "*any* recipient of Federal assistance," and include a broad range of institutions and organizations, the EHA is directed to one class of actors: states and their political subdivisions responsible for providing public education. This accords with the most basic of political knowledge that free public education is provided by and under the aegis of the states.[158]

The First Circuit reasoned that because the state is responsible for guaranteeing both the substantive and procedural rights under the EHA, "Congress intended that the State should be named as an opposing party, if not the sole party, to [a court proceeding under the EHA]."[159]

Although the court in *David D.* did not directly address a suit for monetary relief against a state entity, its analysis of congressional abrogation of immunity under the EHA did demonstrate that where a statute is enacted pursuant to congressional authority under the fourteenth amendment to regulate state public education, Congress is exclusively addressing the states and intending to strip them of their eleventh amendment immunity to suit in federal court.

Education has been viewed by the Supreme Court in *Brown v. Board of Education*[160] as perhaps the most important function of state and local governments. Therefore, the importance of the right to an education has often tipped the balance between states and individuals in favor of individual rights. In *Griffith v. County School Board of Prince Edward County*,[161] the Supreme Court viewed the state's denial to students of a free, public education as a denial of equal protection of the laws as guaranteed by the fourteenth amendment, and as an act from which the states were not immune to suits in federal court under the eleventh amendment.[162] A denial of a free public education to the handicapped was the evil addressed by Congress under the EHA, therefore the states

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157. *David D.*, 775 F.2d at 421. *See* Smith v. Robinson, 468 U.S. 992, 1009 (1984).

158. *David D.*, 775 F.2d at 422 (emphasis in original). *See* 20 U.S.C. §§ 1412, 1413 (1982).

159. *David D.*, 775 F.2d at 442.

160. 347 U.S. 483, 493 (1954).

161. 377 U.S. 218 (1963).

162. *Id.* at 225, 228. *Cf.* Palmer v. Thompson, 403 U.S. 217, 221 (1970) (Supreme Court held closing of public swimming pools instead of desegregating them was not a denial of equal protection of the laws).

should not be immune from suits in federal court brought for violations of this Act. The Third Circuit and lower courts in fact have used *David D.*'s equal protection analysis to allow suits for monetary relief against state entities in federal court.[163]

This Note will now turn to an examination of the EHA's language, which has been ignored by most courts up to this point. The lack of full analysis of EHA language is disconcerting because close inspection demonstrates that Congress clearly intended to abrogate the states' eleventh amendment immunity to effectuate the purposes of the Act. It has not been disputed that based upon section 1400(b)(9) of the EHA and that section's interpretation in *Smith v. Robinson*,[164] the EHA was enacted pursuant to the enforcement authority of Section 5 of the fourteenth amendment.[165] Therefore, the EHA is not a mere funding statute, but creates an enforceable substantive right in handicapped children to a free appropriate public education.[166] This makes state consent to suit in federal court unnecessary as the state has waived its immunity through ratification of the fourteenth amendment.[167] Therefore, the EHA falls under the second category of cases in which eleventh amendment immunity can be abrogated to enforce the substantive provisions of the fourteenth amendment.

The statutory language of the EHA is replete with references to states and state agencies in addition to the equal protection language found in section 1400(b)(9). First, "State"[168] and "State educational agency"[169] are defined terms within the meaning of the Act. Further, the term "free appropriate public education" is defined as "special education and related services which . . . meet the standards of the State educational agency."[170]

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163. *See, e.g.*, Muth v. Central Bucks School Dist., 839 F.2d 113 (3d Cir. 1988); Barwacz v. Michigan Dep't of Educ., 674 F. Supp. 1296, (W.D. Mich. 1987); Antkowiak v. Ambach, 653 F. Supp. 1405 (W.D.N.Y. 1987); John H. v. Brunelle, 631 F. Supp. 208 (D.N.H. 1986).

164. 468 U.S. 992 (1984).

165. 468 U.S. at 1009-111; 20 U.S.C. § 1400(b)(9) (1982). *See David D.* 775 F.2d 940; Antkowiak v. Ambach, 653 F. Supp. at 1418.

166. *See* Honig v. Doe, 108 S. Ct. 592 (1988).

167. *See supra* notes 93-96 and accompanying text.

168. 20 U.S.C. § 1401(6) (1982 & Supp. 1985):

> The term "State" means any of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, or the Trust Territory of the Pacific Islands.

169. 20 U.S.C. § 1401(7) (1982):

> The term "State educational agency" means the State board of education or other agency or officer primarily responsible for the State supervision of public elementary and secondary schools, or, if there is no such officer or agency, an officer or agency designated by the Governor or by State law.

170. 20 U.S.C. § 1401(18)(B) (1982). *See* David D. v. Dartmouth School Comm., 775 F.2d 411, 414 (1st Cir. 1986), *cert. denied*, 475 U.S. 1140 (1986).

Accordingly, unlike section 504 of the Rehabilitation Act which is addressed to any recipient of federal assistance, the EHA is exclusively addressing states and state agencies.

More importantly, section 1411 (entitled "Entitlements and allocations") deals exclusively with how federal funds are allotted to states under the EHA,[171] and how states must distribute those funds to local and intermediate educational agencies within that state.[172] Thus, in contrast to the Rehabilitation Act, where a variety of organizations and institutions receive funds under the Act, states are the only entities which directly receive funds under the EHA. The Supreme Court held in *Burlington* that local educational agencies must reimburse parents for inappropriate placements with funds distributed by the states to the local educational agencies pursuant to the Act.[173] To then state that a state agency is not liable for any reimbursement of similar federal funds for affirming an inappropriate placement is clearly an inconsistent result, as it can clearly be seen that all of these funds under the EHA are originally distributed solely to the several states. The Third Circuit has held in *Muth v. Central Bucks School District*[174] that the eleventh amendment does not bar state reimbursement of a child's educational expenses.[175] The court followed the rationale of the First Circuit in *David D. v. Dartmouth School Committee* that states and state agencies must be accountable for their actions under the EHA "because the EHA and its legislative history reflect the 'most basic of political knowledge that free public education is provided by and under the aegis of the state.'"[176]

Sections 1412, 1413 and 1414 of the EHA extensively address the affirmative duties placed on state educational agencies in order to maintain eligibility for funds provided under the EHA. For example, section 1412(6) provides:

> The State educational agency shall be responsible for assuring that the requirements of this subchapter are carried out and that all educational programs for handicapped children within the State, . . . will be under the general supervision of the persons responsible for educational programs for handicapped children in the State educational agency and shall meet education standards of the State educational agency.[177]

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171. 20 U.S.C. § 1411(a)(1) (1982 & Supp. 1985).
172. *Id.* at §§ 1411(b) and (c).
173. *Burlington*, 471 U.S. at 370-71.
174. 839 F.2d 113 (3d Cir. 1988).
175. *Id.* at 129-30.
176. *Id.* at 129 (quoting David D. v. Dartmouth School Comm., 775 F.2d 411, 422 (1st Cir. 1985)).
177. 20 U.S.C. § 1412(6) (1982). *See supra* note 18.

Finally, section 1415(a) provides that "[a]ny *State* educational agency . . . which receives assistance under [the EHA] shall establish and maintain procedures [in accordance with this section] to assure that handicapped children and their parents or guardians are guaranteed procedural safeguards."[178] Section 1415(e)(2) provides:

> Any party aggrieved by the findings and decision made under subsection (b) of this section [which provides for hearings on complaints by a *State*, local or intermediate educational agency] who does not have the right to an appeal under subsection (c) of this section, *and* any party aggrieved by the findings and decision under subsection (c) of this section [which applies exclusively to *State* review of local educational agency decisions], shall have the right to bring a civil action with respect to the complaint presented pursuant to this section, which action may be brought in any State court of competent jurisdiction or in a district court of the United States without regard to the amount in controversy.[179]

Thus, an action under section 1415(e)(2) can only be maintained against state and local educational agencies. As the Seventh Circuit in *Gomez* found under the EEOA, to hold that Congress did not abrogate the state's eleventh amendment immunity from suits for monetary relief in federal court under the EHA would, in practice, make states and state agencies effectively able to avoid the federal enforcement of the procedural safeguards found in the EHA.[180] To argue that the procedural safeguards found in the EHA could still be enforced against state entities in state court is illusory. Congress clearly did not intend handicapped children's rights to a free appropriate public education to depend on their parent's choice of forum.[181] The First Circuit stated in *David D.* that:

> Congress contemplated, and due process requires, that a consistent body of law would be applied throughout all stages of the due process hearing system. Congress intertwined federal and state standards into one body of law, and did not leave EHA cases dependent upon whether an appeal is taken to a state or federal court.[182]

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178. *Id.* § 1415(a).

179. *Id.* § 1415(e)(2) (emphasis added).

180. *See* Gomez v. Illinois State Bd. of Educ., 811 F.2d 1038 (7th Cir. 1987).

181. *See* David D. v. Dartmouth School Comm., 775 F.2d 411, 419 (1st Cir. 1985), *cert. denied*, 475 U.S. 1140 (1986).

182. *Id. Cf.* Textile Workers Union v. Lincoln Mills, 353 U.S. 448, 457 (1957) (a similar type of incorporation of state and federal standards is found in the National Labor Relations Act, 29 U.S.C. § 301 (1982)).

Unlike statutes, such as the Rehabilitation Act, which provide for relief against "any recipient of Federal assistance,"[183] which recipients may or may not include states and their agencies, the EHA provides for suits against only the decisions of state, intermediate and local educational agencies.[184] Therefore, the EHA expressly contemplates that state and state agency decisions are to be the basis for suits in federal court.

Pursuant to the regulations promulgated under this Act, the state educational agency is characterized as the central point of responsibility and accountability under the EHA, so that failure to deliver services or violations of handicapped children's rights are squarely the responsibility of the state agency.[185] The Supreme Court held in *Hutto v. Finney*[186] that the Civil Rights Attorney's Fees Awards Act of 1976 (section 1988)[187] abrogated state immunity to suit in federal court because section 1988 "primarily applies to laws passed specifically to restrain state action."[188] The EHA's primary and *only* application is to restrain state action to assure a free appropriate education for handicapped children. To hold the states unaccountable for their acts in this situation would clearly render nugatory the express terms of the Act.[189]

The conclusion that Congress effectively abrogated states' immunity from suit in federal court is further strengthened by the recent passage of two federal statutes. The first, the Handicapped Children's Protection Act of 1986, was discussed above and was enacted to reestablish Congress' original intent that parents of handicapped children "must be able to access the full range of available remedies in order to protect their handicapped children's educational rights under the EHA."[190] Further, pursuant to Congress' enactment of section 1415(f) to the EHA, as part of the Handicapped Children's Protection Act of 1986,[191] there is now an express private right of action in the EHA.[192]

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183. 42 U.S.C. § 2000d-7 (1982 & Supp. 1986).

184. 20 U.S.C. §§ 1400-1485 (1982 & Supp. 1985).

185. Assistance to States for Education of Handicapped Children, 34 C.F.R. § 300.600 (1988). *See* S. REP. No. 168, 94th Cong., 1st Sess. 24 (1975).

186. 437 U.S. 678 (1977).

187. Pub. L. No. 94-559, 90 Stat. 2641 (1976) (codified at 42 U.S.C. § 1988 (1982)).

188. *Hutto*, 437 U.S. at 693-94. *See* United States v. Union Gas Co., 792 F.2d 372, 377-78 (3d Cir. 1986) (Third Circuit held that *Hutto* retained its precedential value even after *Atascadero* because it was not overturned).

189. *See, e.g.*, 20 U.S.C. § 1415(e)(2). It would indeed be an awkward reading of this section to interpret it as meaning a judicial review of local hearing appeals under 20 U.S.C. § 1415(b)(2) could be heard in state or federal court, while judicial review of state hearing appeals under 20 U.S.C. § 1415(c) could only be heard in state court, because a request for monetary relief might be involved which would take away federal jurisdiction.

190. S. REP. No. 112, 99th Cong., 1st Sess. 17 (1985), *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS 1798, 1806 (additional views of Senators Kerry, Kennedy, Pell, Dodd, Simon, Metzenbaum, and Matsunga).

191. 20 U.S.C.A. § 1415(f) (West Supp. 1988).

192. *See* Mrs. W. v. Tirozzi, 832 F.2d 748, 751 (2d Cir. 1987).

The second is the civil rights remedies provision included in the Rehabilitation Act Amendments of 1986.[193] In this amendment, states' eleventh amendment immunity was abrogated under the Rehabilitation Act as well as several other statutes. This provision was seen by Senator Lowell Weicker, one of the co-sponsors of the Amendments, as a provision to close "a gap in civil rights protections by allowing individuals to enforce their rights in Federal court when State or State agency actions are at issue."[194]

This amendment is important because it legislatively overruled the decision in *Atascadero* as it applied to the Rehabilitation Act. Congress made it clear during the enactment of this amendment that it was overruling the Supreme Court's misinterpretation of congressional intent under the Rehabilitation Act.[195] This bolsters the *Atascadero* dissent's view that perhaps the special statutory draftsmanship rules in the area of eleventh amendment immunity are in fact being used by the Court to ignore true congressional intent.[196]

IV. Conclusion

The impact of the *Atascadero* "express waiver-abrogation" requirement reaches not only the EHA, but all existing federal statutes as well as all state constitutional and statutory provisions. As for state constitutional and statutory provisions, a state must now specifically indicate a willingness to be sued in federal court. *Atascadero* thus clearly implicates that a general waiver of immunity in a state constitution or statute is no longer sufficient. *Atascadero*, and the subsequent decision of the Court

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192. *See* Mrs. W. v. Tirozzi, 832 F.2d 748, 751 (2d Cir. 1987).

193. Pub. L. 99-506, § 1003, 100 Stat 1807, 1845 (1986) (codified at 42 U.S.C.A. § 2000d-7 (West Supp. 1988)) provides:

> (1) A state shall not be immune under the Eleventh Amendment of the Constitution of the United States from suit in Federal court for a violation of section 794 of Title 29, title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, title VI of the Civil Rights Act of 1964, or the provisions of any other Federal statute prohibiting discrimination by recipients of Federal financial assistance.
>
> (2) In a suit against a State for a violation of a statute referred to in paragraph (1), remedies (including remedies both at law and in equity) area available for such a violation to the same extent as such remedies are available for such a violation in the suit against any public or private entity other than a State.

194. 132 Cong. Rec. S12,096-97 (daily ed. September 8, 1986) (statement of Sen. Weicker).

195. *See, e.g.*, 132 Cong. Rec. S12,099 (daily ed. September 8, 1986) (statement of Sen. Simon).

196. *See supra* notes 61-62 and accompanying text.

in *Welch*, have also eliminated a constructive waiver of a state's immunity based on its participation in federally funded or regulated activities unless Congress expressly conditions participation in the federal program on a state's waiver of immunity.

However, the Court continues to recognize congressional abrogation of immunity under fourteenth amendment legislation where Congress unmistakably expresses its intent to abrogate the immunity within the statute itself. Although this test is more stringent than prior tests for abrogation, its standard is not unambiguous.

The right to an education is one of our nation's most cherished and ardently protected rights. In the EHA, Congress sought to protect the handicapped from the denials of a free public education that stymied their advancement and potential. Congress tied the EHA's protection to a comprehensive scheme of substantive rights enforceable through detailed procedural safeguards. Congress further realized that citizens would need to enforce the mandate of the Act privately, and, therefore, it amended the Act to award attorney's fees to prevailing plaintiffs.

Congress enacted the EHA to assure the handicapped were guaranteed equal protection of the laws under the fourteenth amendment. Although a state's amenability to suits under the EHA would inevitably impinge upon their state autonomy, a far greater harm will occur if the courts refuse to hold states accountable for their acts, as states are primarily and ultimately responsible for instituting the Act's programs and policies. Overtechnical application of the rules of statutory draftsmanship used to find abrogation must not be used by the courts to undermine the express intent of Congress to ensure the handicapped both an equal right to a free public education and an access to the full range of available remedies to protect that right.

Cynthia Pearson Purvis

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